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(54) **Title:** RAPID DEPLOYMENT PROSTHETIC HEART VALVE

(57) **Abstract:** A two-stage or component-based valve prosthesis that can be quickly and easily implanted during a surgical procedure is provided. The prosthetic valve comprises a support structure that is deployed at a treatment site. The prosthetic valve further comprises a valve member configured to be quickly connected to the support structure. The support structure may take the form of a stent that is expanded at the site of a native valve. If desired, the native leaflets may remain and the stent may be used to hold the native valve open. In this case, the stent may be balloon expandable and configured to resist the powerful recoil force of the native leaflets. The support structure is provided with a coupling means for attachment to the valve member, thereby fixing the position of the valve member in the body. The valve member may be a non- expandable type, or may be expandable from a compressed state to an expanded state. The system is particularly suited for rapid deployment of heart valves in a conventional open-heart surgical environment.

WO 2006/127756 A2

RAPID DEPLOYMENT PROSTHETIC HEART VALVE

Related Applications

[0001] The present invention claims priority to Provisional Application No. 60/684,443, filed on May 24, 2005, entitled "Prosthetic Valve for Implantation in a Body Channel."

Field of the Invention

[0002] The present invention generally relates to prosthetic valves for implantation in body channels. More particularly, the present invention relates to prosthetic heart valves configured to be surgically implanted in less time than current valves.

Background of the Invention

[0003] Due to aortic stenosis and other heart valve diseases, thousands of patients undergo surgery each year wherein the defective native heart valve is replaced by a prosthetic valve, either bioprosthetic or mechanical. When the valve is replaced, surgical implantation of the prosthetic valve typically requires an open-chest surgery during which the heart is stopped and patient placed on cardiopulmonary bypass (a so-called "heart-lung machine"). In one common surgical procedure, the diseased native valve leaflets are excised and a prosthetic valve is sutured to the surrounding tissue at the valve annulus. Because of the trauma associated with the procedure and the attendant duration of extracorporeal blood circulation, some patients do not survive the surgical procedure or die shortly thereafter. It is well known that the risk to the patient increases with the amount of time required on extracorporeal circulation. Due to these risks, a substantial number of patients with defective valves are deemed inoperable because their condition is too frail to withstand the procedure. By some estimates, about 30 to 50% of the subjects suffering

from aortic stenosis who are older than 80 years cannot be operated on for aortic valve replacement.

[0004] Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For instance, U.S. Patent No. 5,411,552 to Andersen et al. describes a collapsible valve percutaneously introduced in a compressed state through a catheter and expanded in the desired position by balloon inflation. Although these remote implantation techniques have shown great promise for treating certain patients, replacing a valve via surgical intervention is still the preferred treatment procedure. One hurdle to the acceptance of remote implantation is resistance from doctors who are understandably anxious about converting from an effective, if imperfect, regimen to a novel approach that promises great outcomes but is relatively foreign. In conjunction with the understandable caution exercised by surgeons in switching to new regimens of heart valve replacement, regulatory bodies around the world are moving slowly as well. Numerous successful clinical trials and follow-up studies are in process, but much more experience with these new technologies will be required before they are completely accepted. One question that remains unanswered is whether the new expandable valves will have the same durability as conventional prosthetic heart valves.

[0005] Accordingly, there is a need for an improved device and associated method of use wherein a prosthetic valve can be surgically implanted in a body channel in a more efficient procedure that reduces the time required on extracorporeal circulation. It is desirable that such a device and method be capable of helping patients with defective valves that are deemed inoperable because their condition is too frail to withstand a lengthy conventional surgical procedure. The present invention addresses this need.

Summary of the Invention

[0006] Various embodiments of the present invention provide prosthetic valves and methods of use for replacing a defective native valve in a human heart. Certain embodiments are particularly well adapted for use in a surgical procedure for quickly and easily replacing a heart valve while minimizing time using extracorporeal circulation (i.e., bypass pump).

[0007] In one embodiment, a method for treating a native aortic valve in a human heart, comprises: 1) accessing a native valve through an opening in a chest; 2) advancing an expandable support structure to the site of a native aortic valve, the support structure being radially compressed during the advancement; 3) radially expanding the support structure at the site of the native aortic valve; and 4) mechanically coupling a valve member to the expanded support structure, wherein the valve member replaces the function of the native aortic valve. A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

[0008] In one variation, the support structure is a stent, which may comprise a metallic frame. In one embodiment, at least a portion of the metallic frame is made of stainless steel. In another embodiment, at least a portion of the metallic frame is made of a shape memory material. The valve member may take a variety of forms. In one preferred embodiment, the valve member comprises biological tissue. The valve member further comprises a coupling portion configured to be connected to the support structure in a quick and efficient manner. In another variation of this method, the metallic frame is viewed under fluoroscopy during advancement of the prosthetic valve toward the native aortic valve.

[0009] The native valve leaflets may be removed before delivering the prosthetic valve. Alternatively, the native leaflets may be left in place to

reduce surgery time and to provide a stable base for fixing the support structure within the native valve. In one advantage of this method, the native leaflets recoil inward to enhance the fixation of the metallic frame in the body channel. When the native leaflets are left in place, a balloon or other expansion member may be used to push the valve leaflets out of the way and thereby dilate the native valve before implantation of the support structure.

[0010] In another preferred embodiment, a method for treating a native aortic valve in a human heart, comprises accessing a native valve through an opening in a chest; advancing an expandable member to a position within the native aortic valve, the native aortic valve having at least two valvular leaflets; dilating the native aortic valve by expanding the expandable member to push aside the valvular leaflets of the native aortic valve; collapsing the expandable member and withdrawing the expandable member from the native aortic valve; advancing an expandable support structure to a position within the dilated native aortic valve, the support structure being radially compressed during the advancement; radially expanding the support structure within the dilated aortic valve, wherein the expanded support structure maintains the native aortic valve in the dilated condition; and coupling a valve member to the expanded support structure, wherein the valve member replaces the function of the native aortic valve.

[0011] In another aspect, an improved prosthetic valve comprises an expandable stent sized for implantation at the site of a native aortic valve, the stent having a coupling means (e.g., a plurality of tines extending from a first end thereof); and a valve member comprising three leaflets mounted on a base portion. The coupling means is configured for attachment to the valve member. Alternatively, the coupling means may be provided on the valve member or on both the stent and valve member.

[0012] A particularly useful configuration of the present invention is a two-stage prosthetic heart valve, comprising an expandable anchoring member

sized to contact a heart valve annulus in an expanded state and a substantially non-expandable valve member configured for connection to the anchoring member. Desirably, the valve member includes a base ring surrounding an inflow end thereof, and the anchoring member comprises a tubular structure having connectors adapted to engage the base ring. The connectors may comprise prongs that change shape and engage the base ring. For example, the base ring may be made of a suture-permeable material, and the prongs are configured to pierce the base ring, or the prongs are shaped to wrap around the base ring.

[0013] In an exemplary embodiment, the valve member includes a plurality of discrete connectors spaced around a peripheral inflow end thereof, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof. The connectors on the valve member and anchoring member engage one another by displacing the valve member toward the anchoring member. For instance, the connectors on either the valve member or anchoring member comprise latches, and the connectors on the other of the valve member or anchoring member comprise brackets, the latches configured to engage and lock to the brackets upon axial movement of the latches and brackets toward one another. Additionally, a plurality of guide filaments may be provided, at least one for each of the connectors on the anchoring member and slidingly received by the associated connector on the valve member. The guide filaments guide the valve member in proper orientation with respect to the anchoring member to ensure engagement of the mating connectors.

[0014] Desirably, the anchoring member comprises a stent having a wider outflow end than an inflow end thereof, wherein the valve member comprises a base ring surrounding an inflow end thereof that fits within the outflow end of the stent. In one embodiment, the valve member includes a suture-permeable base ring surrounding an inflow end thereof, and the

anchoring member comprises a tubular structure having a suture-permeable fixation ring attached thereto, wherein the valve member connects to the anchoring member via sutures looped between the base ring and the fixation ring.

[0015] Another embodiment of the present invention comprises a two-stage prosthetic heart valve, having an expandable anchoring member sized to contact a heart valve annulus in an expanded state, a valve member, and an adapter sized to surround the valve member and engage the anchoring member, to connect the valve member and anchoring member. The adapter may be an annular ring or a wireform-shaped member that closely surrounds and conforms to cusps and commissures of a flexible leaflet valve member.

[0016] Whatever its shape, the adapter desirably includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof. The connectors on the adapter and anchoring member are configured to engage one another by displacing the adapter toward the anchoring member. For example, the connectors on either the adapter or anchoring member comprise latches, and the connectors on the other of the adapter or anchoring member comprise brackets, the latches being configured to engage and lock to the brackets upon axial movement of the latches and brackets toward one another. In addition, the valve member preferably has a base ring surrounding an inflow end thereof, and the adapter further includes a plurality of connectors adapted to engage and couple the adapter directly to the base ring.

[0017] Another aspect of the present invention is a system for retrofitting a conventional prosthetic heart valve, comprising an off-the-shelf, non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through the sewing ring in an open-heart procedure. An expandable anchoring member contacts and anchors to a heart valve

annulus in an expanded state. Coupling means connects the prosthetic heart valve to the anchoring member, the prosthetic heart valve thus being attached to the heart valve annulus via the anchoring member.

[0018] In the system for retrofitting a conventional prosthetic heart valve, the anchoring member may comprise a tubular structure having a suture-permeable fixation ring attached thereto, wherein the coupling means comprises sutures looped between the base ring and the fixation ring. An adapter sized to surround the heart valve engages the anchoring member, to connect the heart valve and anchoring member. The adapter may be annular or wireform-shaped. Desirably, the adapter includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof, the connectors on the adapter and anchoring member being configured to engage one another by displacing the adapter toward the anchoring member.

[0019] A surgical method of implanting a prosthetic heart valve of the present invention in a patient involves providing a two-stage prosthetic heart valve comprising an expandable anchoring member and a valve member, the anchoring member being sized to contact a heart valve annulus in an expanded state and the valve member being configured to connect to the anchoring member. The patient is prepared for surgery by placing him/her on cardiopulmonary bypass. The surgeon creates a direct access pathway to the heart valve annulus that preferably permits direct (i.e., naked eye) visualization of the heart valve annulus. The anchoring member is delivered and expanded to contact the valve annulus, and the valve member is delivered and connected to the anchoring member. Preferably, the direct access pathway is created by performing open-heart surgery. The method may include balloon-expanding the anchoring member. Further, the valve member may be expandable and the method includes delivering the valve member in a

compressed state and expanding it prior to connecting it to the anchoring member.

[0020] In one embodiment, the valve member and the anchoring member are provided with mating connectors, and the step of delivering and connecting the valve member to the anchoring member comprises axially displacing the valve member toward the anchoring member so that the mating connectors engage. In another embodiment, the anchoring member comprises a stent having an outflow end larger than an inflow end thereof, and the valve member comprises a non-expandable valve member having a base ring on an inflow end thereof sized to fit within the outflow end of the stent. The anchoring member may be provided with bendable connectors on an outflow end thereof, and the method includes causing the connectors to bend inward and engage a peripheral base ring of the valve member. For example, a bending tool may be used to bend connectors inward.

[0021] Another surgical method of implanting a two-stage prosthetic heart valve in a patient of the present invention includes providing an expandable anchoring member sized to contact a heart valve annulus in an expanded state, delivering and attaching the anchoring member to the heart valve annulus, providing a non-expandable valve member, and delivering and connecting the valve member to the anchoring member. The valve member and the anchoring member may be provided with mating connectors, and the step of delivering and connecting the valve member to the anchoring member comprises axially displacing the valve member toward the anchoring member so that the mating connectors engage. Desirably, the anchoring member comprises a stent having an outflow end larger than an inflow end thereof, and wherein the valve member comprises a base ring on an inflow end thereof sized to fit within the outflow end of the stent. The anchoring member may be provided with bendable connectors on an outflow end thereof, and the method

includes causing the connectors to bend inward and engage a peripheral base ring of the valve member, such as by using a bending tool.

[0022] In an exemplary embodiment, the valve member includes a base ring on an inflow end thereof, and the method further includes providing an adapter sized to surround the valve member and seat on the base ring. The method therefore includes the step of delivering and connecting the valve member and coupling the adapter to the anchoring member. For instance, the adapter includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof. The step of coupling the adapter to the anchoring member comprises displacing the adapter toward the anchoring member to engage the mating connectors thereon. Additionally, the adapter may further have a plurality of connectors adapted to engage and couple the adapter directly to the base ring, and the method includes causing the connectors to engage the base ring.

[0023] In a still further surgical method of implanting a prosthetic heart valve in a patient, a prosthetic heart valve and a separate expandable anchoring member are provided. The prosthetic heart valve and anchoring member are positioned within a valve dilator/delivery tube having an exterior diameter sized to dilate a heart valve annulus. The valve dilator/delivery tube advances to the heart valve annulus, and the annulus is dilated using the valve dilator/delivery tube. The anchoring member is expulsed from the tube and expanded to contact the heart valve annulus. The prosthetic heart valve is then expulsed from the valve dilator/delivery tube, and connected to the anchoring member.

[0024] Another method of the present invention comprises retrofitting and rapidly implanting a conventional prosthetic heart valve in a patient. The method includes providing an off-the-shelf non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through

the sewing ring in an open-heart procedure. An expandable tissue anchoring member sized to contact a heart valve annulus in an expanded state is delivered and expanded into contact with the heart valve annulus. Finally, the prosthetic heart valve is delivered and connected to the tissue anchoring member.

Brief Description of the Drawings

[0025] The invention will now be explained and other advantages and features will appear with reference to the accompanying schematical drawings wherein:

[0026] Figure 1 is an exploded perspective view illustrating a preferred embodiment of a two-stage prosthetic valve comprising a stent portion and a valve member, wherein the valve member may be quickly and easily connected to the stent portion.

[0027] Figure 2 illustrates the valve embodiment of Figure 1 after the valve member has been attached to the stent portion by crimping portions of the stent over the commissural points of the valve member.

[0028] Figure 3 is an exploded perspective view of an alternative embodiment wherein the stent is provided with a plurality of tines configured to be crimped to a ring along the base of the valve member.

[0029] Figure 4 illustrates the valve embodiment of Figure 3 after the valve member has been attached to the stent portion by crimping the tines on to the valve member.

[0030] Figure 4A is a sectional view through one side of the prosthetic heart valve of Figure 4 taken along line 4A-4A and showing one configuration of tines connecting through a sewing ring portion of the valve member.

[0031] Figure 5 is an exploded perspective view of an alternative embodiment wherein slotted posts are provided on the stent for coupling to protruding members on the valve member.

[0032] Figure 5A is an enlarged view of one of the slotted posts provided on the stent of Figure 5.

[0033] Figures 6 and 6A illustrate another alternative embodiment similar to Figures 5 and 5A wherein the posts are configured with L-shaped slots for locking the valve member to the stent.

[0034] Figure 7 is a sectional view through a body channel that illustrates an alternative embodiment of prosthetic heart valves wherein first and second stents are provided for anchoring a valve member within the body channel.

[0035] Figure 8 is an exploded perspective view of an alternative embodiment wherein the stent has a small diameter and a large diameter and wherein an expandable valve member is deployed within the large diameter.

[0036] Figure 9A is an exploded perspective view of another alternative embodiment of a two part prosthetic valve wherein a ring portion along the base of the valve member snaps into a groove formed in the stent.

[0037] Figure 9B illustrates the embodiment of Figure 9A with the valve member connected to the stent.

[0038] Figure 10 is an exploded perspective view of another alternative embodiment wherein the valve member and the stent are provided with corresponding threaded portions for threadably engaging the valve member to the stent.

[0039] Figure 11 is an exploded perspective view of an alternative prosthetic heart valve of the present invention having a valve member, stent, and a threaded locking ring for coupling the two together.

[0040] Figures 12A and 12B are exploded and assembled perspective views of an alternative two-stage prosthetic heart valve having a valve member and tubular, expandable stent with tabs on an outflow end for coupling to the valve member.

[0041] Figures 12C and 12D are sectional views through one side of the prosthetic heart valve of Figure 12B schematically illustrating an exemplary tool that may be used to bend the tabs on the outflow end of the stent around a sewing ring of the valve member.

[0042] Figures 13A and 13B are exploded and assembled perspective views of an alternative prosthetic heart valve of the present invention wherein a valve member and stent with tabs are coupled together in conjunction with a locking ring.

[0043] Figures 14A and 14B are exploded and assembled perspective views of a still further prosthetic heart valve wherein a valve member and tubular, expandable stent are coupled together using a wireform-shaped adapter having tabs.

[0044] Figures 15A and 15B are exploded and assembled perspective views of a prosthetic heart valve having a valve member and stent with locking bands on an outflow end.

[0045] Figures 16A and 16B are exploded and assembled perspective views of an alternative prosthetic heart valve wherein a stent exhibits locking clips on an outflow end that are guided through mating slits on a locking ring to join the stent to a valve member.

[0046] Figures 17A and 17B are exploded and assembled perspective views of an alternative prosthetic heart valve wherein a stent has brackets on an outflow end that receive guided locking clips on a locking ring to join the stent to a valve member.

[0047] Figure 18 is a perspective view of an alternative stent for use in a prosthetic heart valve of the present invention.

[0048] Figure 19 is a detailed sectional view through an inflow side of a prosthetic heart valve utilizing the stent of Figure 18 and showing a valve member base ring captured between two sets of prongs.

[0049] Figure 20 is a perspective exploded view of a prosthetic heart valve having a tubular stent with upstanding tines and a valve member with an additional adapter ring arranged around a base ring.

[0050] Figure 21 is an exploded perspective view of an exemplary prosthetic heart valve having an expandable stent and non-expandable valve member connected by an array of parachute sutures being removed from a storage jar.

[0051] Figures 22A-22C are several views of the implantation of the prosthetic heart valve of Figure 21 assisted by a tubular valve dilator/delivery tube.

Detailed Description of the Preferred Embodiments

[0052] The present invention attempts to overcome drawbacks associated with conventional, open-heart surgery, while also adopting some of the techniques of newer technologies which decrease the duration of the treatment procedure. The prosthetic heart valves of the present invention are primarily intended to be delivered and implanted using conventional surgical techniques, including the aforementioned open-heart surgery. There are a number of approaches in such surgeries, all of which result in the formation of a direct access pathway to the particular heart valve annulus. For clarification, a direct access pathway is one that permits direct (i.e., naked eye) visualization of the heart valve annulus. In addition, it will be recognized that embodiments of the two-stage prosthetic heart valves described herein may also be configured for delivery using percutaneous approaches, and those minimally-invasive surgical approaches that require remote implantation of the valve using indirect visualization.

[0053] One primary aspect of the present invention is a two-stage prosthetic heart valve wherein the tasks of implanting a tissue anchor and a valve member are somewhat separated and certain advantages result. For

example, a two-stage prosthetic heart valve of the present invention may have an expandable tissue anchoring member that is secured in the appropriate location using a balloon or other expansion technique. A valve member is then coupled to the tissue anchoring member in a separate or sequential operation. By utilizing an expandable anchoring member, the duration of the initial anchoring operation is greatly reduced as compared with a conventional sewing procedure utilizing an array of sutures. The expandable anchoring member may simply be radially expanded outward into contact with the implantation site, or may be provided with additional anchoring means, such as barbs. The operation may be carried out using a conventional open-heart approach and cardiopulmonary bypass. In one advantageous feature, the time on bypass is greatly reduced due to the relative speed of implanting the expandable anchoring member.

[0054] For definitional purposes, the term "tissue anchoring member," or simply "anchoring member" refers to a structural component of a heart valve that is capable of attaching to tissue of a heart valve annulus. The anchoring members described herein are most typically tubular stents, or stents having varying diameters. A stent is normally formed of a biocompatible metal wire frame, such as stainless steel or Nitinol. Other anchoring members that could be used with valves of the present invention include rigid rings, spirally-wound tubes, and other such tubes that fit tightly within a valve annulus and define an orifice therethrough for the passage of blood, or within which a valve member is mounted. It is entirely conceivable, however, that the anchoring member could be separate clamps or hooks that do not define a continuous periphery. Although such devices sacrifice some dynamic stability, these devices can be configured to work well in conjunction with a particular valve member.

[0055] The term "valve member" refers to that component of a heart valve that possesses the fluid occluding surfaces to prevent blood flow in one

direction while permitting it in another. As mentioned above, various constructions of valve numbers are available, including those with flexible leaflets and those with rigid leaflets or a ball and cage arrangement. The leaflets may be bioprosthetic, synthetic, or metallic.

[0056] A primary focus of the present invention is the two-stage prosthetic heart valve having a first stage in which an anchoring member secures to a valve annulus, and a subsequent second stage in which a valve member connects to the anchoring member. It should be noted that these stages can be done almost simultaneously, such as if the two components were mounted on the same delivery device, or can be done in two separate clinical steps, with the anchoring member deployed using a first delivery device, and then the valve member using another delivery device. It should also be noted that the term "two-stage" does not necessarily limit the valve to just two parts, as will be seen below.

[0057] Another potential benefit of a two-stage prosthetic heart valve, including an anchoring member and a valve member, is that the valve member may be replaced after implantation without replacing the anchoring member. That is, an easily detachable means for coupling the valve member and anchoring member may be used that permits a new valve member to be implanted with relative ease. Various configurations for coupling the valve member and anchoring member are described herein.

[0058] It should be understood, therefore, that certain benefits of the invention are independent of whether the anchoring member or valve member are expandable or not. That is, various embodiments illustrate an expandable anchoring member coupled to a conventional valve member. However, the same coupling structure may be utilized for a non-expandable anchoring member and conventional valve member. Additionally, although a primary embodiment of the present invention is an expandable anchoring member coupled with a conventional valve member, both could be expandable and

introduced percutaneously or through a minimally-invasive approach. Therefore, the invention should not be construed as being limited in these regards, but instead should be interpreted via the appended claims.

[0059] As a point of further definition, the term "expandable" is used herein to refer to a component of the heart valve capable of expanding from a first, delivery diameter to a second, implantation diameter. An expandable structure, therefore, does not mean one that might undergo slight expansion from a rise in temperature, or other such incidental cause. Conversely, "non-expandable" should not be interpreted to mean completely rigid or a dimensionally stable, as some slight expansion of conventional "non-expandable" heart valves, for example, may be observed.

[0060] In the description that follows, the term "body channel" is used to define a blood conduit or vessel within the body. Of course, the particular application of the prosthetic heart valve determines the body channel at issue. An aortic valve replacement, for example, would be implanted in, or adjacent to, the aortic annulus. Likewise, a mitral valve replacement will be implanted at the mitral annulus. Certain features of the present invention are particularly advantageous for one implantation site or the other. However, unless the combination is structurally impossible, or excluded by claim language, any of the heart valve embodiments described herein could be implanted in any body channel.

[0061] With reference now to Figure 1, one preferred embodiment of an improved prosthetic valve 10 generally includes an expandable anchoring member or stent 20 and a valve member 30. The stent provides a support structure for anchoring the valve member within a body lumen. Although a stent is described for purposes of illustration, any support structure capable of anchoring the valve member to the body lumen may be used. As will be described in more detail below, the prosthetic valve is configured such that the valve member may be quickly and easily connected to the stent. It should be

noted here, that the anchoring members or stents described herein can be a variety of designs, including having the diamond-shaped openings shown or other configurations detailed below. The material depends on the mode of delivery (i.e., balloon- or self-expanding), and the stent can be bare strut material or covered to promote in-growth and/or to reduce paravalvular leakage. For example, a suitable cover that is often used is a sleeve of fabric such as Dacron.

[0062] The stent may be securely deployed in the body channel using an expandable member, such as, for example, a balloon. Because the stent is expanded before the valve member is attached, the valve member will not be damaged or otherwise adversely affected during the stent deployment. After the stent has been deployed in the body channel, the valve member may be connected to the stent. In one preferred application, the two-stage prosthetic valve is well-suited for use in heart valve replacement. In this application, the stent may be advantageously used to push the native leaflets aside such that the valve member can replace the function of the native valve. The anchoring members or stents described herein could include barbs or other such tissue anchors to further secure the stent to the tissue. In one preferred embodiment, the barbs are deployable (e.g., configured to extend or be pushed radially outward) by the expansion of a balloon.

[0063] In another advantageous feature, the two-stage prosthetic valve illustrated in Figure 1 provides a device and method for substantially reducing the time of the surgical procedure. This reduces the time required on extracorporeal circulation and thereby substantially reduces the risk to the patient. The surgical time is reduced because the stent may be deployed quickly and the valve member may be attached to the stent quickly. This simplifies and reduces the surgical time as compared with replacement valves that are sutured to the tissue after removing the native leaflets.

[0064] When used for aortic valve replacement, the valve member 30 preferably has three leaflets 36 which provide the valvular function for replacing the function of the native valve. In various preferred embodiments, the valve leaflets may be taken from another human heart (cadaver), a cow (bovine), a pig (porcine valve) or a horse (equine). In other preferred variations, the valve member may comprise mechanical components rather than biological tissue. In one preferred embodiment, the valve is compressible in diameter. Accordingly, the valve may be reduced in diameter for delivery into the stent and then expanded. The three leaflets are supported by three commissural posts 34. A ring 32 is provided along the base portion of the valve member.

[0065] With continued reference to Figure 1, the stent 20 is provided with two diameters. A lower portion 22 has a small diameter and an upper portion 24 has a large diameter. The lower portion 22 is preferably sized to be deployed at the location of the native valve (e.g., along the aortic annulus). The upper portion 24 expands outwardly into the perspective cavity adjacent the native valve. For example, in an aortic valve replacement, the upper portion 24 expands into the area of the sinus cavities just downstream from the aortic annulus. Of course, care should be taken to orient the stent 20 so as not to block the coronary openings. The stent body is preferably configured with sufficient radial strength for pushing aside the native leaflets and holding the native leaflets open in a dilated condition. The native leaflets provide a stable base for holding the stent, thereby helping to securely anchor the stent in the body. To further secure the stent to the surrounding tissue, the lower portion may be configured with anchoring members, such as, for example, hooks or barbs (not shown).

[0066] The upper portion 24 of the stent 20 has a larger diameter sized for receiving the valve member 30. A transition region 28 between the upper and lower portions of the stent body may be advantageously used to provide a

seat for the bottom end of the valve member. The stent may further comprise a ridge (not shown) along an inner wall for providing a more definite seat portion within the stent.

[0067] With continued reference to Figure 1, the prosthetic valve 10 is provided with a coupling mechanism for securing the valve member 30 to the stent 20. The coupling mechanism may take a variety of different forms. However, in the illustrated embodiment, the stent body comprises three posts 26 which correspond to the three commissural points 34 on the valve member. The three posts 26 are preferably formed of a malleable material such that the posts 26 may be crimped over the commissural points on the valve member. A bending tool (not shown) may be provided for crimping the posts 26 over the commissures of the valve member, or the posts 26 may be hinged or made of the shape memory material so as to curl once implanted in the body. With reference to Figure 2, the prosthetic valve 10 is illustrated in the assembled condition with the posts 26 crimped over the commissural points 34 of the valve member. In one variation, the three posts on the stent are formed with a recess for receiving the commissural points, such as in a snap-fit relationship.

[0068] In a preferred embodiment, the stent 20 is expandable, but the valve member 30 is a conventional, non-expandable prosthetic heart valve, such as the Carpentier-Edwards PERIMOUNT Magna® Aortic Heart Valve available from Edwards Lifesciences of Irvine, California. In this sense, a "conventional" prosthetic heart valve is an off-the-shelf (i.e., suitable for stand-alone sale and use) non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through the sewing ring in an open-heart procedure. An implant procedure therefore involves first delivering and expanding the stent 20 and the aortic annulus, and then coupling the valve member 30 thereto. Because the valve member 30 is non-expandable, the entire procedure is typically done using the conventional open-heart technique. However, because the stent 20 is delivered and

implanted by simple expansion, the entire operation takes less time. This hybrid approach will also be much more comfortable to surgeons familiar with the open-heart procedures and conventional heart valves. Moreover, the relatively small change in procedure coupled with the use of proven heart valves should create a much easier regulatory path than strictly expandable, remote procedures.

[0069] A variation of the embodiment described in Figures 1 and 2 may incorporate an expandable stent 20 and an expandable valve member 30. Although not shown, the valve member 30 may be capable of expansion within the body, such as the Cribier-Edwards Aortic Percutaneous Heart Valve, also available from Edwards Lifesciences. Therefore, the valve 10 may be implanted without an open-heart procedure, and even without stopping heart. In such a remote procedure, the three posts 26 on the stent 20 may be made of a shape memory material having a temperature-induced shape change once implanted. Alternatively, a tool for bending the posts 26 may be delivered along with the valve 10 and utilized when the valve member 30 seats within the stent 20.

[0070] With reference now to Figure 3, an alternative prosthetic valve 10A comprises a stent 40 provided with a bottom portion 42 and an upper flared portion 44. A plurality of prongs or tines 46 is disposed along a top end of the flared portion 44. The tines 46 are preferably bendable members configured to engage the ring portion 32 along the base of the valve member 30. In one preferred embodiment, the tines 46 are crimped over the ring as shown in Figure 4. If desired, the tines 46 may have pointed tips for passing through a fabric or other similar material along the ring portion of the valve member, such as seen in Figure 4A.

[0071] Once again, the stent 40 is desirably an expandable member that can be easily delivered and implanted at the body channel. The valve member 30 may be conventional, or may also be expandable. The illustrated

embodiment shows a conventional valve 30 having the sewing ring portion 32 surrounding an inflow end. Sewing rings are typically made of suture-permeable material covered with cloth. The tines 46 may be sharp enough to pierce the material of the sewing ring portion 32 (Figure 4A). In this regard, a conventional valve member 30 may be utilized without modification. In the alternative, the sewing ring portion 30 may be replaced with a more rigid peripheral band or ring, and the tines 46 are simply bent inward so as to fold over the ring and capture the valve member 31 on the top of the stent 40. Desirably, a seat or rim of some sort is provided within the interior of the stent 40 so that the valve member 30 can easily be positioned therein. The tines 46 may be mechanically bent using a deployment tool (not shown), or they may be hinged or made of a shape memory material so as to curl inward upon reaching a certain temperature.

[0072] With reference now to Figure 5, another alternative prosthetic valve 10B comprises an anchoring member or stent 50 provided with a cylindrical portion 52 and three posts 54 extending upward from the cylindrical portion. Each post 54 may be slotted, as illustrated in the enlarged view of Figure 5B, or formed with an orifice. Radially protruding members 38 are provided along the ring portion 32 of the valve member 30 for mating with the posts on the stent. The exemplary slot has a thin neck portion 58 wherein engagement members, such as angled teeth, are provided. The teeth are angled such that the slot widens as the protruding member 38 is pushed downward into the slot. After passing through the teeth into the capture portion 59, the protruding member 38 is securely captured. Because the teeth are angled in only one direction, an upward force will not cause the slot to widen, thereby capturing the protruding member.

[0073] With reference now to Figure 6, yet another alternative embodiment of a component prosthetic valve 10C is illustrated. The embodiment of Figure 6 is similar to the embodiment illustrated and described

above with respect to Figure 5. However, in this variation, the posts or connecting members 55 are provided with L-shaped slots 57 for receiving the protruding member disposed along the valve member. With reference to Figure 6A, an enlarged view of one preferred connecting member 55 is shown. The slot 57 of the connecting member 55 is shaped such that the protruding member 38 moves longitudinally into the slot and then rotationally to enter the capture portion. One or more teeth 58 may be provided for holding the protruding member in the capture portion. Alternatively, the protruding member 38 may be held in the slot 57 using friction or a mechanical locking member. In another alternative, a key lock system or "bayonet" attachment mechanism may be provided for coupling the valve member to the stent.

[0074] With reference now to Figure 7, another alternative prosthetic valve 10D is illustrated wherein the valve member 30 is captured and held between first and second stents 60, 62. In use, the first stent 60 is expanded within a body channel such that the outer surface of the stent is in contact with the vessel wall 64. The valve member 30 is then advanced through the body channel and into contact with the first stent. A ring 32 is preferably provided along the base portion of the valve member for contacting the outflow end of the first stent. The second stent is then advanced through the body channel and is deployed such that an inflow end of the second stent contacts a top surface of the ring 32 of the valve member for anchoring the valve member between the first and second stents.

[0075] The embodiment of Figure 7 employs a slightly different means for connecting the valve member 30 the anchoring member. Primarily, stents 60, 62 capture the ring 32 of the valve member 30 therebetween simply by providing upper and lower barriers to movement. The valve member 30 is desirably a non-expandable type, therefore the ring 32 is not overly susceptible to compression. By providing sufficient of the thickness of the stents 60, 62, the valve member 30 remains sandwiched therebetween. In this regard, the

outflow end of the first stent 60 and the inflow end of the upper stent 62 are preferably flat or blunt so as not to dig into the ring 32. Because of the anchoring function of the stents 60, 62, there is no need to suture the valve member 30, and thus the ring 32 may be made relatively firm or rigid. Alternatively, the facing edges of the stents 60, 62 may be provided with barbs or other such piercing devices, and the ring 32 provided as a conventional suture-permeable sewing ring.

[0076] As noted above, the anchoring members or stents described herein could include barbs or other anchors to further secure the stent to the tissue. Further, the barbs could be deployable (e.g., configured to extend or be pushed radially outward) by the expansion of a balloon. Likewise, the stent can be covered to promote in-growth and/or to reduce paravalvular leakage. The cover would be similar to those on other valves, e.g., a Dacron tube or the like.

[0077] Alternatively, the valve member may be constructed with a tubular frame or cage for engaging one or both stents 60, 62. In various preferred embodiments, the stents may be self-expanding or balloon-expandable. In one advantageous feature, the valve member 30 of this embodiment is not required to be mounted within a cylindrical frame or stent. Accordingly, the flow through area of the valve member may be maximized to improve valve function. In another variation, the first and second stents may be integrated as a single unit forming a chamber therebetween. In this variation, the valve member may be expanded within the chamber for securely deploying the valve member in the body channel.

[0078] With reference now to Figure 8, another alternative embodiment of a two-stage prosthetic valve 10E is illustrated wherein the anchoring member or stent 70 is provided with a varying diameter. More particularly, a lower portion 72 of the stent has a small diameter sized for implantation at a native valve annulus. In one preferred configuration, the

small diameter is about 23 mm. The stent also has an upper portion 74 with a larger diameter for receiving an expandable valve member 30A. In one preferred configuration, the larger diameter is about 29 mm. In this embodiment, the valve member 30A is provided as a tubular body that is radially expandable. The valve leaflets are disposed along the interior of the valve member.

[0079] The stent 70 preferably includes a circular ridge 76 formed along the transition region between the large and small diameters. The ridge provides a seat for the base of the valve member 30A. In one preferred embodiment, the ridge 76 incorporates a support wire 78 that extends at least partially through the ridge for strength and may be used to provide a radiopaque marker. The remaining portion of the ridge may be formed of Dacron or any other suitable material. The stent 70 may be comprised of a screen or mesh. A cover 75, such as a polymer sheet, may be provided along at least a portion of the stent to help prevent leakage and enhance sealing. In addition, a sponge or cloth may be provided along the exterior portion of the stent for further enhancing sealing.

[0080] The stent 70 of Figure 8 may be self-expanding or balloon-expandable. When provided as a balloon-expandable stent, a expandable tapered (i.e., two diameter) balloon may be provided for deploying the stent. When configured for use with a stent having diameters of 23 mm and 29 mm, the balloon may have diameters of 22 mm and 28 mm, respectively.

[0081] With reference now to Figures 9A and 9B, another alternative embodiment of a component prosthetic valve 10F is provided wherein a valve member 30 is configured for connection with an anchoring member or stent 90. In this embodiment, the stent 90 is provided with a groove 94 formed in an inwardly-directed circumferential member 92. The groove extends at least partially around the inner portion of the stent and is sized to receive the ring portion 32 of the valve member 30. In one preferred embodiment, the ring is

configured to snap fit into the groove, as seen in Figure 9B. In another variation, the ring is made of a shape memory material configured to expand after deployment in the body. In this variation, the ring is configured to radially expand for securely anchoring itself within the groove.

[0082] With reference now to Figure 10, yet another alternative embodiment of a component prosthetic valve 10G is illustrated wherein the valve member 30 is configured for threadable engagement with an anchoring member or stent 100. In this embodiment, the stent is provided on one end with a threaded region 102 along an inner wall configured for receiving a threaded flange portion 33 on the valve member 30. The threaded flange portion is preferably provided along the ring 32 at the base of the valve member. During use, the stent is first deployed in the body channel. The stent may be deployed in a manner wherein the diameter of the threaded region remains substantially constant so as to not affect the threads. In one embodiment, the stent is substantially non-expandable and is delivered into the lumen in its fully expanded condition. This can be achieved by first stretching or dilating the delivery site for receiving the stent. In another embodiment, only the lower portion of the stent is expanded for engaging the tissue. In either embodiment, the valve member is threadably attached to the threaded flange on the stent after the stent has been firmly anchored in the body channel. This attachment means is configured such that the valve member advantageously connects to the stent through rotational movement. Accordingly, longitudinal forces applied to the valve member after implantation will have little or no effect on the integrity of the connection between the stent and valve.

[0083] With reference now to Figure 11, an alternative prosthetic heart valve 10H comprises a valve member 30, an anchoring member or stent 110, and a locking ring 112. As before, the stent 110 desirably expands first at the implantation site, after which a conventional valve member 30 couples to the

stent through the use of the locking ring 112. However, the valve member 30 may also be expandable, and the stent 110 can take a variety of forms. In a preferred embodiment, the stent 110 comprises a latticework of balloon-expandable members adapted to be delivered to the implantation site in a collapsed or compressed state, and then expanded from within using a balloon. Of course, a self-expanding stent 110 could also be used, and additional anchoring means of such as exterior barbs may be provided to help prevent the stent from migrating after implantation.

[0084] A series of tabs or flanges 114 project slightly inwardly from an outflow end of the stent 110. The flanges 114 are configured to mate with exterior threading 116 on a downwardly-projecting shoulder of the locking ring 112. The number and configuration of the flanges 114 is selected to avoid interfering with radial expansion of the stent 110, and also to mate with the threads 116 of the locking ring 112. Desirably, a series of space-apart flanges 114, for example eight, evenly spaced around the outflow rim of the stent 110 project inward therefrom a distance of between 1-3 mm.

[0085] An inner bore 118 of the locking ring 112 possesses a diameter large enough to pass over the entire valve member 30 except for the base ring 32, which could be a sewing ring of a conventional heart valve. When coupled together, the locking ring 112 surrounds the valve member 30 and desirably includes an inner ledge that rests on the base ring 32 thereof. The inner diameter of the shoulder having the exterior threading 116 is sized larger than the base ring 32 and extends downwardly into engagement with the flanges 114. By screwing down the locking ring 112, the components can be easily and rapidly assembled. After implantation, removal and replacement of the valve member 30 merely requires releasing the locking ring 112 from any tissue ingrowth, unscrewing and removing it, and releasing the valve member 30 from the stent 110 by cutting away any tissue ingrowth therebetween.

[0086] Figures 12A and 12B illustrate another prosthetic heart valve 10I of the present invention having an expandable anchoring member or stent 120 coupled to a valve member 30. Much like the valve 10A of Figures 3 and 4, the outflow end of the stent 120 exhibits a series of spaced-apart tabs 122 that curl around the base ring 32 of the valve member 30. In this embodiment, the stent 120 is a straight tube, and there are fewer tabs 122 (e.g., eight) than there are tines 46 in the valve 10A. The tabs 122 may be bent using an auxiliary tool (not shown), or may possess a property permitting autonomous bending, such as temperature-induced movement.

[0087] Figures 12C and 12D are sectional views through one side of the prosthetic heart valve 10I of Figure 12B schematically illustrating an exemplary tool that may be used to bend the tabs 122 on the outflow end of the stent 120 around the base ring 32 of the valve member 30. It should be noted that the section is taken radially through one side of the system, and the tool will typically be annular or at least peripherally arranged to bend each one of the tabs 122. The tool comprises a forming member 124 having a forming surface 125. The forming member 124 slides within and relative to an outer anvil 126 having an inwardly angled portion 128 that directly surrounds and engages each of the tabs 122. The forming surface 125 is curved such that axial displacement of the forming member 124 in the direction shown in Figure 12C curls each of the tabs 122 inward to the shape of Figure 12D. In this embodiment, the tabs 122 wrap over the top of and restrain the base ring 32. In other embodiments, the tool may be used to bend prongs so that they pierce the base ring 32. It should be noted that the outer anvil 126 is primarily used for centering purposes to guide the forming member 124 toward the tabs 122.

[0088] Figures 13A and 13B illustrate another embodiment of a prosthetic valve 10J having multiple components joined together. An anchoring member or stent 130 includes a plurality of tangs or flanges 132 on

an outflow end. A valve member 30 seats adjacent the outflow end of the stent 130, and a fixation ring 134 extends therearound. Additionally, a plurality of tabs 136 project downward from the fixation ring 34. Although not shown, the tabs 136 enable the fixation ring 34 to be coupled to the base ring 32 of the valve member 30 by mechanically bending the tabs, or configuring the tabs to curl upon reaching a certain temperature. As seen in Figure 13B, the flanges 132 extend around the outside of the fixation ring 134 and bend around the upper or outflow end thereof. Again, this can be accomplished using an auxiliary tool or through temperature-induced movement. Alternatively, the flanges 132 may be formed of a resilient polymer or metal having the shape seen in Figure 13B such that they can be flexed outward around the fixation ring 134 and then snapped back into place to secure the ring around the valve member 30. Although not shown, the interior of the fixation ring 134 is desirably contoured to mate with the base ring 32 of the valve member 30. The fixation ring 134 can be made of any number of materials, including rigid, flexible, metallic, polymer, bioabsorbable, etc. One preferred configuration is a Teflon ring coated with anti-thrombogenic or anti-microbial compositions.

[0089] Figure 14A illustrates a still further prosthetic heart valve 10K having an expandable anchoring member or stent 140, a valve member 30, and a wireform-shaped adapter 142. The stent 140 and valve member 30 have been previously described. The adapter 142 has a shape similar to a so-called "wireform" used in the internal construction of many prior art bioprosthetic tissue valves. Indeed, the valve member 30 is desirably a Carpentier-Edwards PERIMOUNT Magna® Aortic Heart Valve made by Edwards Lifesciences, and including therewithin an Elgiloy wireform. The adapter 142 may be formed of biocompatible polymers or metals, preferably an alloy such as Nitinol.

[0090] The adapter 142 carries a plurality of securing tabs 144, 146. In the illustrated embodiment, three lower securing tabs 144 are located at the apex of the three cusps of the wireform-shape, and two upper securing tabs 146 are located at each of the upstanding commissures of the wireform-shape, for a total of six at the commissures. Figure 14B is a detailed illustration of the assembly of the stent 140, valve member 30, and adapter 142. The base ring 32 of the valve member 30 seats on or just within the outflow end of the stent 140, and the adapter 142 fits over the valve member and couples to it, as well as to the stent. In this regard, the cusps of the adapter 142 seat on or slightly outside the base ring 32 with the commissures surrounding and conforming to the commissures of the valve member 30. The cusp securing tabs 144 bend up over the base ring 32 and down into engagement with the stent 140. The two securing tabs 146 at each commissure of the adapter 142 bend or wrap around the corresponding valve member commissure.

[0091] Again, a supplemental tool may be used to accomplish the bending of the securing members 144, 146, or they may exhibit temperature-changing properties. In the illustrated embodiment, the securing tabs 144, 146 are malleable, though other configurations are within the scope of the invention. For example, the lower securing tabs 144 may be barbs or tangs which pierce the base ring 32 and hook around the stent 140, while the upper securing tabs 146 may be resilient straps that wrap around each one of the commissures of the valve member 30.

[0092] To further secure the valve member 30 to the stent 140, the stent includes a plurality of upstanding barbs 147 comprising spaced apart posts having teeth 140. The adapter 142 possesses a plurality of outwardly projecting brackets 149 defining slots therethrough. As seen in Figure 14B, the barbs 147 pass through the base ring 32 and through the slots of the brackets 149 in the adapter 142. The teeth 148 prevent removal of the barbs

147 from the slots. In this way, the stent 140 and adapter 142 are securely connected together, sandwiching the valve member 30 therebetween.

[0093] Another possibility is that the securing tabs 144, 146 are not initially carried by the adapter 142, but instead are added after the assembly of the three components. For instance, staples or even sutures may be used after the valve member 30 seats on the stent 140, and the adapter 142 is lowered around the valve member. Even if sutures are used, the time required relative to a conventional sewing operation is greatly reduced. Moreover, the structural support and anchoring properties of the wireform-shaped adapter 142 greatly enhances the overall integrity of the assembly. In this regard, securing tabs such as those shown may be placed more continuously around the adapter 142 so as to provide more uniform contact with the valve member 30. One possible configuration is a series of small hooks or brackets extending along the undulating adapter 142 that loop over the corresponding undulating shape on the valve member 30. The valve member 30 is therefore restrained from upward movement relative to the adapter simply by lowering the adapter 142 over the valve member. In such an arrangement, only the lower securing members need be actively attached, such as by causing their shape to change and bend into engagement with the stent 140, as seen in Figure 14B.

[0094] A further prosthetic valve embodiment 10L seen in Figure 15A includes an expandable anchoring member or stent 150 and a valve member 30. A plurality of fixation straps 152 is disposed along the outflow end of the stent 150. Four such straps 152 are shown; however, in other variations, more or less may be utilized. For example, three straps extending farther around the periphery of the outflow end of the stent 150 may be substituted. Conversely, four or more straps that overlap one another may be used.

[0095] Figure 15B illustrates the valve member 30 seated on top of the stent 150 with one of the straps 152 securing the two components together.

Straps 152 may be attached at both of their ends to the stent 150, and may comprise a resilient biocompatible material that stretches over the base ring 32 of the valve member 30. Alternatively, the straps may be bent or folded over the base ring. In one variation, one end of each strap 152 may be initially free, and after the strap is looped over the base ring 32 is then attached to the stent 150, somewhat like a belt configuration. The straps 152 may be formed of a variety of materials, typically cloth-covered so as to permit tissue ingrowth over a cloth-covered base ring 32 for enhanced long-term anchorage. One possible variation is to incorporate small barbs or Velcro-style hooks in each of the straps 152 so as to gain better purchase on the base ring 32.

[0096] Figures 16A and 16B illustrate a still further embodiment, wherein the prosthetic heart valve 10M comprises a valve member 30, expandable anchoring member or stent 160, and coupling ring 162. The coupling ring 162 defines a series of circumferentially-spaced apertures or slots 164 that receive upstanding hooks or latches 166 on the stent 160. As seen in Figure 16B, the coupling ring 162 surrounds the commissures of the valve member 30 and seats on the base ring 32, and the latches 166 extend through the slots 164 and are secured therein by outwardly directed teeth 168. In the illustrated embodiment, the latches 166 each comprise a pair of parallel, spaced apart upstanding members, each with an outwardly directed tooth 168, which may be cammed inward toward one another as they pass through the slots 164. As the teeth 168 clear the slot 164, the parallel members resiliently spring outward thus latching the stent 160 to the coupling ring 162. The coupling ring 162 may further include a plurality of outwardly projecting tabs 172 that are bent or curl around the base ring 32.

[0097] To aid in guiding the latches 166 through the slots 164, one or more guide members may be used to direct the coupling ring toward the stent such that the slots are aligned with the latch members. For example, in the illustrated embodiment, a plurality of guide filaments 170 are attached to each

one of the upstanding latch members and passed through the corresponding slots. Figure 16A illustrates the pre-assembled valve 10M with the guide filaments 170 extending up through each of the slots 164. The implantation procedure comprises first delivering and expanding the stent 160, and then advancing the valve member 30 to the position shown in Figure 16B. The coupling ring 162 is then parachuted down the array of guide filaments 170, ultimately facilitating passage of the latches 166 through the slots 164. The final assembly is seen in Figure 16B. in a preferred embodiment, each two guide filaments 170 comprises a strand of a single looped passing through small holes in each of the latch members. Removal of the guide filaments 170 is thus a simple matter of just pulling one of the strands, or severing the loop in between the latch members. Note that guide filaments could be used on any of the embodiments described herein to facilitate coupling of the separate components of the prosthetic heart valves. For example, in another variation, a wireform similar to the embodiment illustrated in Figure 14A may also be used with a guiding filament.

[0098] The exemplary embodiment shows the latches 166 extending around the outside of the base ring 32 of the valve member 30. It is entirely feasible, on the other hand, to design the latches 166 to pierce through the base ring 32. Inclusion of the coupling ring 162 is suggested, because of its washer-like function in holding the assembly together. However, the latches 166 may be designed to pierce through and securely fasten to stent 160 to the base ring 32 without the use of the coupling ring 162. In this regard, the latches 166 may be configured differently, or more than the number shown may be provided. For example, 4, 6, 8, or more single latch members having a configuration such as shown with a leading sharp point and rearwardly directed barb (much like a fish hook) could fight adequate anchorage through a conventional base ring 32 made of a silicone sponge covered with cloth.

Those of skill in the art will understand that there are numerous alternatives available.

The stent 160 in Figures 16A and 16B has an outflow end that is preferably sized larger than its inflow end. More particularly, the outflow end is flared so as to receive therein the base ring 32 of the valve member 30. In this way, a larger orifice valve member can be utilized than with a straight tubular stent. The reader is also reminded that at least the flared portion of the stent 160 is desirably provided with a sleeve of Dacron or other such fabric to help prevent paravalvular leaking between the base ring 32 and the surrounding native valve annulus.

[0100] With reference to Figures 17A and 17B, yet another two part prosthetic valve 10N is configured for rapid deployment in a heart for replacing a defective native valve. In this version, an expandable anchoring member or stent 180 couples to a valve member 30 through the use of a coupling ring 182 in a manner similar to the last-described embodiment. The coupling ring 182 carries a plurality of latches 184 which mate with brackets 186 provided on the stent 180. In the illustrated embodiment, the latches 184 again comprise a pair of spaced-apart latch members having outwardly directed teeth 188, and the brackets 186 are simply apertures or slots in material loops that extend outward from the stent 180 adjacent its outflow end. Bringing the three components together, the latches 184 extend through the brackets 186 as seen in Figure 17B. To facilitate proper and rapid passage of the latches 184 through the brackets 186, a plurality of guide filaments 190 loop through the brackets 186 and through holes provided in the latches 184. Simply parachuting the coupling ring 182 down the filaments 190 aims the latches 184 through the brackets 186.

[0101] At this stage, it is important to note that any of the fixation rings (i.e., locking ring 112, fixation ring 134, adapter 142, coupling ring 162, or coupling ring 182) described above could be designed to engage the

surrounding tissue (annulus) and provide additional protection again paravalvular leakage. For example, a tissue growth factor or fibrin glue or the like may be coated on the exterior of any of these fixation rings for a better seal. Alternatively, the fixation rings might have an outer rim of fabric for encouraging tissue ingrowth. Moreover, the various fixation rings described and the base ring 32 of the valve member 32 may be constructed as a single component. For example, the base ring 32 could be configured to have slots (or any coupling member) in lieu of a separate fixation ring.

[0102] With reference now to Figure 18, an alternative expandable anchoring member or stent 200 is illustrated wherein the anchoring member is configured to receive a valve member 30 to form a prosthetic heart valve. As illustrated in Figure 19, a portion of the valve member is gripped between inwardly extending members located within the stent. More particularly, the stent 200 comprises a plurality of axial struts 202 connected by a number of rows of circumferential crown-shaped struts 204 to form a generally tubular structure. A lower or inflow end of the stent 200 includes a circumferential row of crown-shaped struts 206 that is larger than the others such that the inflow end of the stent flares outward. The upper rows 204 of circumferential struts define valleys (pointing downward) at the axial struts 202 and peaks (pointing upward) midway between each two adjacent axial struts. As seen from Figure 18, therefore, the spaces defined between adjacent axial struts 202 and adjacent rows of circumferential struts 204 are preferably chevron-shaped, pointed upward. Conversely, the lower circumferential row of struts 206 has upper peaks at the axial struts 202 and lower valleys therebetween, resulting in elongated hexagon-shaped spaces between the lower two circumferential rows of struts.

[0103] The stent 200 possesses a plurality of prongs that extend inward therefrom to capture the valve member 30. As seen in Figure 19, the base ring 32 of the valve member 30 seats on a plurality of lower prongs 208. Figure 18

shows the lower prongs 208 extending inward from the lower row of struts 206 at the valleys between adjacent axial struts 202. The lower prongs 208 terminate in enlarged heads 210 to prevent damage to the base ring 32. As seen in Figure 19, the lower prongs 208 project inward farther than the expanded to defined by the upper portion of the stent 200. Additionally, a plurality of upper prongs 212 extend inward from one of the upper rows of circumferential struts 204. In the illustrated embodiment, there are four rows of circumferential struts 204, and the upper prongs 212 project inward from the second lowest row. As seen in Figure 19, the upper prongs 212 contact the base ring 32 of the valve member 30. In this manner, the valve member 30 is captured between the lower prongs 208 and upper prongs 212.

[0104] In the illustrated embodiment, the stent 200 includes twelve axial struts 202, and one of each of the prongs 208, 212 between each adjacent pair of axial struts, resulting in twelve each of the lower and upper prongs. Of course, the number of prongs could be more or less depending on the configuration of the stent 200. Further, there may be more than one prong between adjacent pairs of axial struts 202, or the prongs may be provided only between every other pair. The prongs 208, 212 may be initially flat within the profile of the surrounding struts to prevent interference with an expansion-balloon. After stent deployment they may be bent inward into the angles shown using a tool (not shown). Alternatively, the balloon wall could be relatively thick and able to withstand puncture by the round heads of the prongs 208, 212 such that they are at all times biased inward and automatically assume the angles shown after balloon removal.

[0105] To deploy the prosthetic heart valve of Figures 18 and 19, the user advances the stent 200 in a collapsed state through the vasculature or a chest port into the target implantation site. Through self-expansion or balloon-expansion, the stent 200 expands into contact with the surrounding valve annulus. The valve member 30 then advances into position adjacent the

outflow or upper end of the stent 200. Desirably, the valve member 30 is a conventional non-expandable design, but could also be expandable, in which case it is then expanded prior to assembly with the stent 200.

[0106] The outer diameter of the base ring 32 of the valve member 30 is sized approximately the same as the inner diameter of the tubular upper portion of the stent 200. The valve member 30 advances from the outflow end of the stent 200 toward the inflow end until the base ring 32 contacts the circular row of upper prongs 212. The upper prongs 212 are flexible, hinged, or otherwise capable of being displaced outward by the base ring 32 as the valve member 30 passes. Ultimately, the base ring 32 seats on the circular row of relatively non-flexible lower prongs 28 and the valve member 30 cannot be advanced farther. The spacing between the lower prongs 208 and the upper prongs 212 is such that the upper prongs 212 spring inward at the point that the base ring 32 seats on the lower prongs 208. The upper prongs 212 may be formed with blunt heads like the lower prongs 208, or may be straight or even sharp-pointed to pierce the base ring 32 and provided enhanced anchorage. In a preferred embodiment, both the lower prongs 208 and upper prongs 212 possess enlarged, blunt heads such that the base ring 32 is merely trapped between the two sets of prongs.

[0107] The design of the stent 200 of Figure 18 thus enables rapid deployment of a valve member therewithin, as well as positive tactile feedback to the user with valve member 30 is completely installed. Because the base ring 32 is sized closely within the stent 200, good peripheral sealing is provided. To better enhance sealing, a peripheral skirt or layer of graft material may be added on the interior or exterior of the stent 200.

[0108] With reference to Figure 20, another embodiment of a prosthetic heart valve 220 comprises a tubular, expandable anchoring member or stent 222, a valve member 30, and an adapter ring 224 for coupling the two components together. The stent 222 and manner of connecting the stent to the

valve member 30 is similar to embodiment of Figures 3 and 4, and also the embodiment of Figure 12, in that a plurality of tines 226 project upward from the stent 222. However, instead of the tines 226 piercing or curling around the base ring 32 of the valve member 30, the tines interact with the adapter ring 224. In particular, the adapter ring 224 attaches around the lower periphery of the base ring 32, preferably via a secure stitch line formed during assembly of the valve member 30. The tines 226 pierce or otherwise engage the adapter ring 224 instead of the base ring 32 to couple the valve member 30 to the stent 222. The supplemental adapter ring 224 provides an added margin of safety that helps prevent damage to the valve member 30 by the tines 226. For instance, if the tines 226 are configured to pierce and curl inward, they are farther away from the inner flexible leaflets 36 of the valve member which are susceptible to puncture or tearing.

[0109] With reference to Figure 21, yet another embodiment of a prosthetic heart valve 230 comprises an anchoring member or stent 232 coupled to a valve member 30 via a plurality of sutures 234. The components of the valve 230 are shown exploded above a container or jar 236 used to store the components. In this regard, the entire assembly, including the attachment sutures 234, may be stored together in the jar 236 so as to be ready for deployment. Alternatively, only the stent 232 and valve member 30 may be stored in the jar 236, and the sutures 234 added just prior to deployment but before the actual operation. Still further, the stent 232 can be stored dry in a sterile container, while the valve member 30 having bioprosthetic leaflets may be stored separately in a suitable preservative fluid such as glutaraldehyde. In any event, details of the prosthetic heart valve 230 will be described below with reference to Figures 22A through 22C.

[0110] Figures 22A through 22C show the components of the prosthetic heart valve 230 in conjunction with a valve dilator/delivery tube 240. The usage of the delivery tube 240 will be described below. The stent

232 comprises an expandable, tubular structure formed of a plurality of axial struts 242 joined by a plurality of angled circumferential struts 244. In this embodiment, there are four rows of circumferential struts 244, the upper two pointing upward, and the lower to pointing downward. The result is a series of both diamond-shaped and chevron-shaped openings. Three axial bars 246 substitute for the more narrow struts 242 at three evenly-spaced positions around the stent 232. As seen in the view of Figure 22B, the commissures 34 of the valve member 30 align with the axial bars 246.

[0111] With reference now to the sectional view of Figure 22C, the stent 232 additionally comprises an inner fixation ring 250 and an outer sealing ring 252. Both these rings 250, 252 attach to the struts of the stent 232 independently, or to each other through the struts. For example, a series of sutures (not shown) can be used to join the inner ring 250 and outer ring 252 in a relatively continuous circumferential line around the stent 232. These rings are desirably made of suture-permeable, typically compressible material such as silicone rubber, or may be rolled up fabric cuffs. In any event, the inner fixation ring 250 couples to the valve member 30, while the outer sealing ring 252 help prevent leakage around the stent 232.

[0112] As seen in Figure 22A, the attachment sutures 234 extend upward within the stent 232 from the inner fixation ring 250. In this regard, each two strands of the attachment sutures 234 may be defined by looping a single length of suture downward and back upward through the fixation ring 250. The circular array of sutures 234 then passes through corresponding sectors of the base ring 32 of the valve member 30. Again, this can be done at the time of valve assembly, just prior to the valve replacement procedure, or after the stent 232 has been implanted. Those of skill in the art will understand the process of lining up the circular array of attachment sutures 234 into the appropriate locations around the base ring 32 to permit the valve

member 32 to parachute down the sutures until it contacts the fixation ring 250.

[0113] The entire procedure will now be described in conjunction with use of the valve dilator/delivery tube 240. As mentioned above, the valve replacement procedures described herein are sometimes done without removing the existing native valve. The annulus and valve leaflets are often heavily calcified, and sometimes provide a serious impediment to passage and implant of a replacement valve, even a valve that is initially quite small and balloon expanded. To help widened the orifice in which the prosthetic valve 230 will be implanted, the delivery tube 240 receives all of the valve components therein and acts as a protective sleeve and dilator. In a preferred embodiment, just the sealing ring 252 extends out of the delivery tube 240 at an inflow or leading end thereof.

[0114] First, the attachment sutures 234 are preinstalled within the fixation ring 250 and, while maintaining a non-crossing circular array, are passed through the delivery tube 240 to be accessible out the upper end. The sutures 234 are then passed through the appropriate locations within the base ring 32 of the valve member 30. Of course, this can be done during fabrication of the prosthetic heart valve 230, though some structure for maintaining the relative position and orientation of two components is required. In any event, a holder (not shown) attached to the valve member 30 is used to advance the valve member along the array of sutures 234 and within the delivery tube 240, into the approximate position seen in Figure 22A.

[0115] When the patient has been prepared, and an access opening to the target implantation site created, the assembly of the prosthetic heart valve 230 within the delivery tube 240 advances into the body. The leading end comprises the sealing ring 252 and an outwardly bulged portion 254 in the delivery tube 240. For installation in the aortic annulus, the delivery tube 240 advances down the ascending aorta until the stent 232 lines up with the

annulus (with the help of radiopaque markers or the like). The outwardly bulged portion 254 in the delivery tube 240 helps open up the calcified annulus. Even if the native valve is resected, sometimes the annulus will shrink a little prior to implant of the valve. The valve dilator/delivery tube 240 thus helps open up the annulus to permit implant of a desired diameter valve. The contour of the bulged portion 254 is relatively smooth, and the material may be Teflon or other such highly lubricated surface so that the tube easily slips through the annulus. A slight back-and-forth movement may be required to fully open the annulus.

[0116] At this stage, the delivery tube 250 retracts relative to the stent 232, through the use of a pusher (not shown) for example, such that the stent 232 may fully expand into the annulus. The stent 232 may be self-expanding and thus be only partially expanded within the delivery tube 240. When the delivery tube 240 is removed, the stent 232 springs outward into firm engagement with the annulus. Alternatively, a balloon (not shown) may be used to accomplish the final expansion of the stent 232, which configuration would require a catheter passing through the center of the valve leaflets 34. If the stent 232 is balloon expandable, consideration must be taken of the continual attachment of the valve to the guide sutures 234. On the other hand, if the stent 232 is self-expanding, then typically an auxiliary sheath would be provided to hold the stent in the contracted condition.

[0117] When the user is satisfied that the stent 232 is properly positioned, the valve member 30 is advanced using the aforementioned holder (not shown). As the valve member 30 advances, care is taken to ensure that the attachment sutures 234 remain untangled and taut. Ultimately, the valve member 30 seats on the fixation ring 250 as seen in Figures 22B and 22C. At this point, the user ties and severs the attachment sutures 234 in a conventional manner. The provision of the sealing ring 252 directly adjacent and

surrounding the fixation ring 250 greatly enhances the ability of the prosthetic valve 230 to resist paravalvular leaking.

[0118] In one advantageous feature, preferred embodiments of the component based prosthetic valves described herein may be used with existing technology. For example, certain stent embodiments may be configured for attachment to sewing rings provided on existing prosthetic valves. In other cases, valve member require only small variations in order to be used with the component based system. Not only will this contribute to a lower price for the final valve, but also learned familiarity to the system for surgeons who might be hesitant to adopt a completely new system.

[0119] It will be appreciated by those skilled in the art that embodiments of the present invention provide important new devices and methods wherein a valve may be securely anchored to a body lumen in a quick and efficient manner. Embodiments of the present invention provide a means for implanting a prosthetic valve in a surgical procedure without requiring the surgeon to suture the valve to the tissue. Accordingly, the surgical procedure time is substantially decreased. Furthermore, in addition to providing an anchoring member for the valve, the stent may be used to maintain the native valve in a dilated condition. As a result, it is not necessary for the surgeon to remove the native leaflets, thereby further reducing the procedure time.

[0120] It will also be appreciated that the present invention provides an improved system wherein a valve member may be replaced in a more quick and efficient manner. More particularly, it is not necessary to cut any sutures in order to remove the valve. Rather, the valve member may be disconnected from the stent (or other support structure) and a new valve member may be connected in its place. This is an important advantage when using biological tissue valves or other valves having limited design lives. Still further, it will be appreciated that the devices and methods of the present invention may be configured for use in a minimally invasive approach (e.g., through a small

incision between the ribs) or in a percutaneous procedure while still remaining within the scope of the invention.

While the invention has been described in its preferred embodiments, it is to be understood that the words which have been used are words of description and not of limitation. Therefore, changes may be made within the appended claims without departing from the true scope of the invention.

WHAT IS CLAIMED IS:

1. A two-stage prosthetic heart valve, comprising:

an expandable anchoring member sized to contact a heart valve annulus in an expanded state; and

a non-expandable valve member configured for connection to the anchoring member.

2. The heart valve of claim 1, wherein the valve member includes a base ring surrounding an inflow end thereof, and the anchoring member comprises a tubular structure having connectors adapted to engage the base ring.

3. The heart valve of claim 2, wherein the connectors comprise prongs that change shape and engage the base ring.

4. The heart valve of claim 3, wherein the base ring is made of a suture-permeable material, and the prongs are configured to pierce the base ring.

5. The heart valve of claim 3, wherein the prongs are shaped to wrap around the base ring.

6. The heart valve of claim 1, wherein the valve member includes a plurality of discrete connectors spaced around a peripheral inflow end thereof, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof, the connectors on the valve member and anchoring member being configured to engage one another by displacing the valve member toward the anchoring member.

7. The heart valve of claim 6, wherein the connectors on either the valve member or anchoring member comprise latches, and the connectors on the other of the valve member or anchoring member comprise brackets, the latches being configured to engage and lock to the brackets upon axial movement of the latches and brackets toward one another.

8. The heart valve of claim 6, further including a plurality of guide filaments, at least one for each of the connectors on the anchoring member and slidingly received by the associated connector on the valve member for guiding the valve member in proper orientation with respect to the anchoring member to ensure engagement of the mating connectors.

9. The heart valve of claim 1, wherein the anchoring member comprises a stent having a wider outflow end than an inflow end, and wherein the valve member comprises a base ring surrounding an inflow end thereof, the base ring being sized to fit within the outflow end of the stent.

10. The heart valve of claim 1, wherein the valve member includes a suture-permeable base ring surrounding an inflow end thereof, and the anchoring member comprises a tubular structure having a suture-permeable fixation ring attached thereto, wherein the valve member connects to the anchoring member via sutures looped between the base ring and the fixation ring.

11. A two-stage prosthetic heart valve, comprising:

an expandable anchoring member sized to contact a heart valve annulus in an expanded state;

a valve member; and.

an adapter sized to surround the valve member and engage the anchoring member for connecting the valve member to the anchoring member.

12. The heart valve of claim 11, wherein the adapter comprises an annular ring.

13. The heart valve of claim 11, wherein the valve member comprises flexible leaflets and a plurality of alternating cusps and upstanding commissures, and the adapter comprises a wireform-shaped member that closely surrounds and conforms to the cusps and commissures of the valve member.

14. The heart valve of claim 11, wherein the adapter includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof, the connectors on the adapter and anchoring member being configured to engage one another by displacing the adapter toward the anchoring member.

15. The heart valve of claim 14, wherein the valve member includes a base ring surrounding an inflow end thereof, and the adapter further includes a plurality of connectors adapted to engage and couple the adapter directly to the base ring.

16. The heart valve of claim 14, wherein the connectors on either the adapter or anchoring member comprise latches, and the connectors on the other of the adapter or anchoring member comprise brackets, the latches being

configured to engage and lock to the brackets upon axial movement of the latches and brackets toward one another.

17. The heart valve of claim 14, further including a plurality of guide members, at least one for each of the connectors on the anchoring member and slidingly received by the associated connector on the adapter for guiding the adapter in proper orientation with respect to the anchoring member to ensure engagement of the mating connectors.

18. A system for retrofitting a conventional prosthetic heart valve, comprising:

an off-the-shelf, non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through the sewing ring in an open-heart procedure;

an expandable anchoring member sized to contact and anchor to a heart valve annulus in an expanded state; and

coupling means for connecting the prosthetic heart valve to the anchoring member, the prosthetic heart valve thus being attached to the heart valve annulus via the anchoring member.

19. The system of claim 18, wherein the anchoring member comprises a tubular structure having a suture-permeable fixation ring attached thereto, wherein the coupling means comprises sutures looped between the base ring and the fixation ring.

20. The system of claim 18, further including an adapter sized to surround the heart valve and engage the anchoring member, to connect the heart valve and anchoring member.

21. The heart valve of claim 20, wherein the adapter is selected from the group consisting of:

an annular ring; and

a wireform-shaped member.

22. The heart valve of claim 20, wherein the adapter includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof, the connectors on the adapter and anchoring member being configured to engage one another by displacing the adapter toward the anchoring member.

23. The heart valve of claim 20, wherein the adapter further includes a plurality of connectors adapted to engage and couple the adapter directly to the sewing ring.

Fig. 1

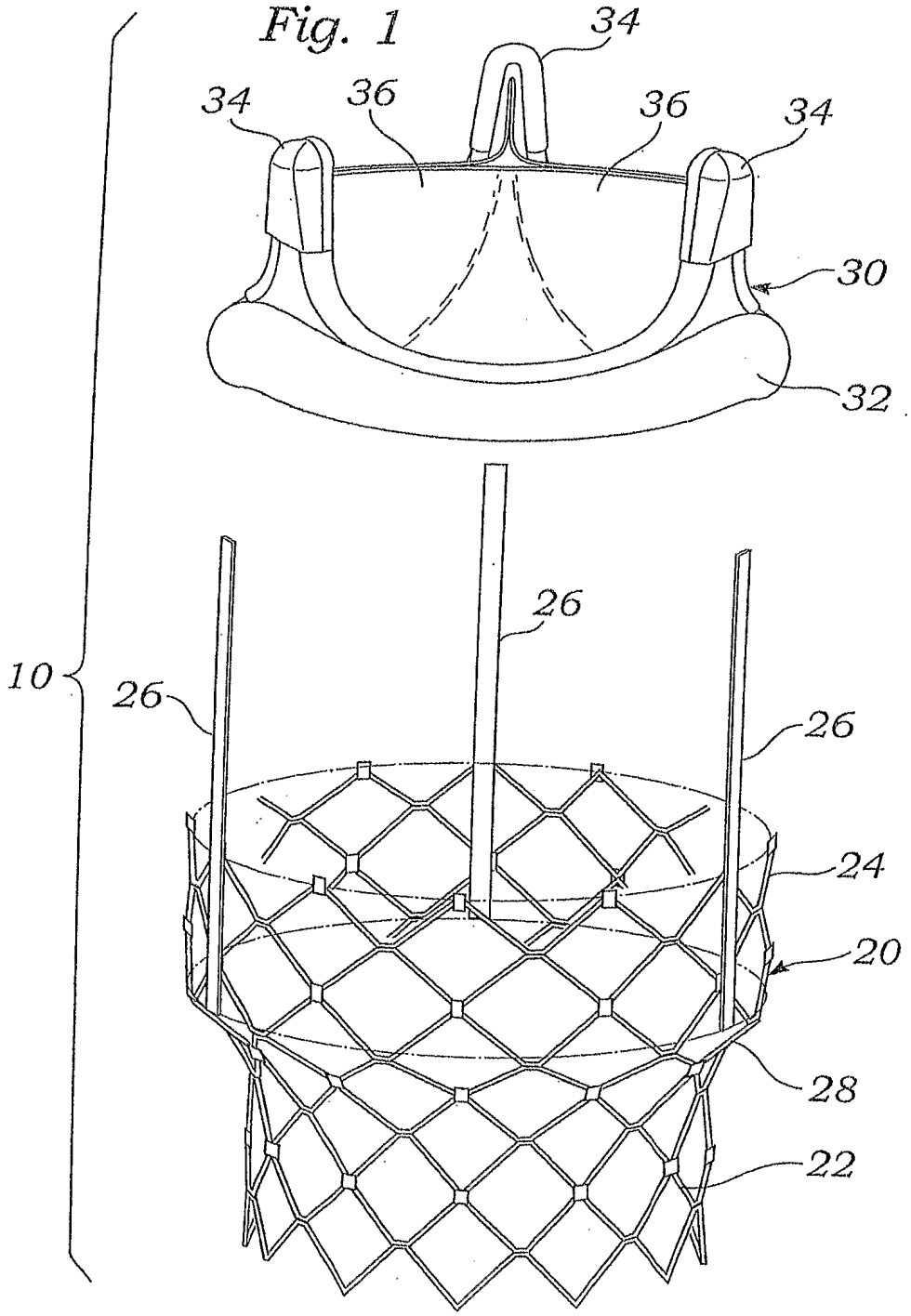


Fig. 2

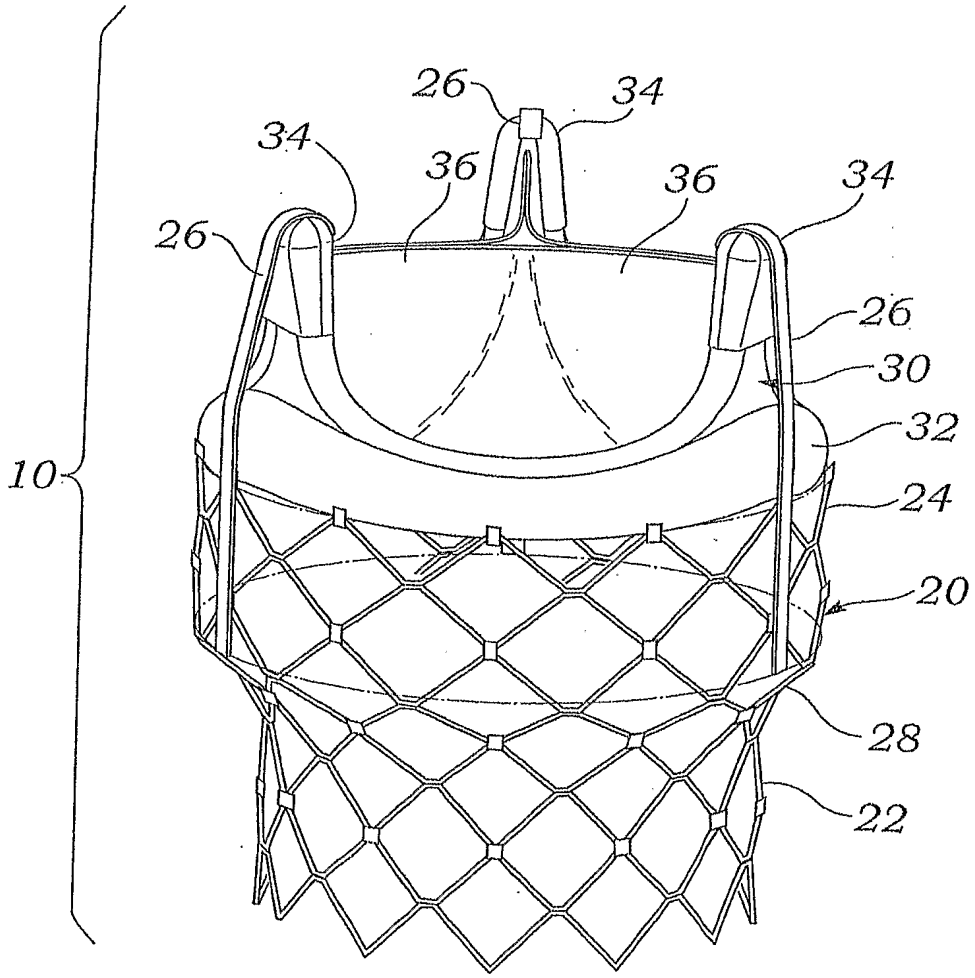


Fig. 3

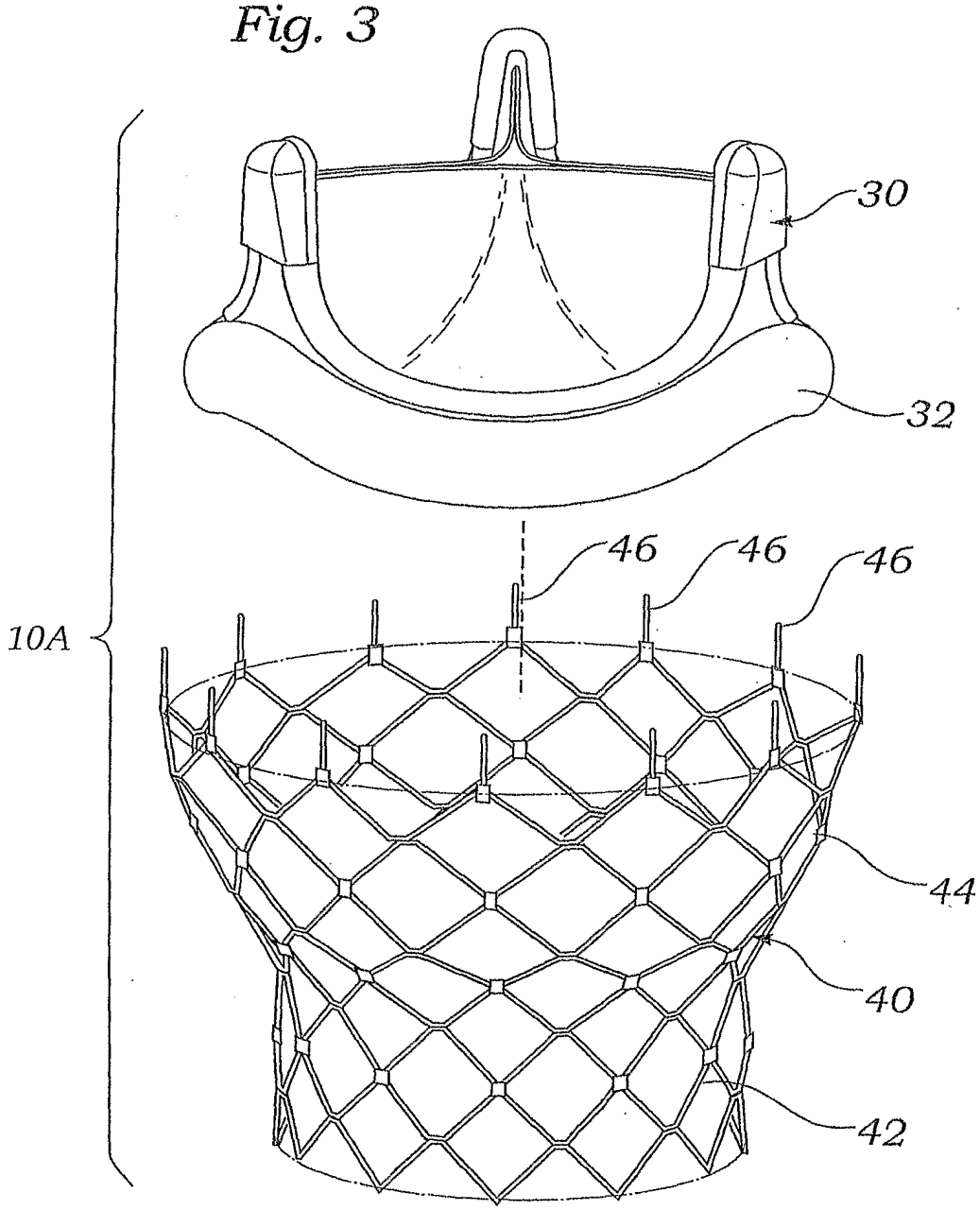


Fig. 4A

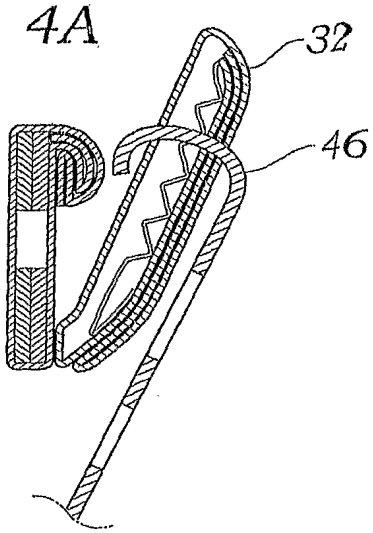


Fig. 4

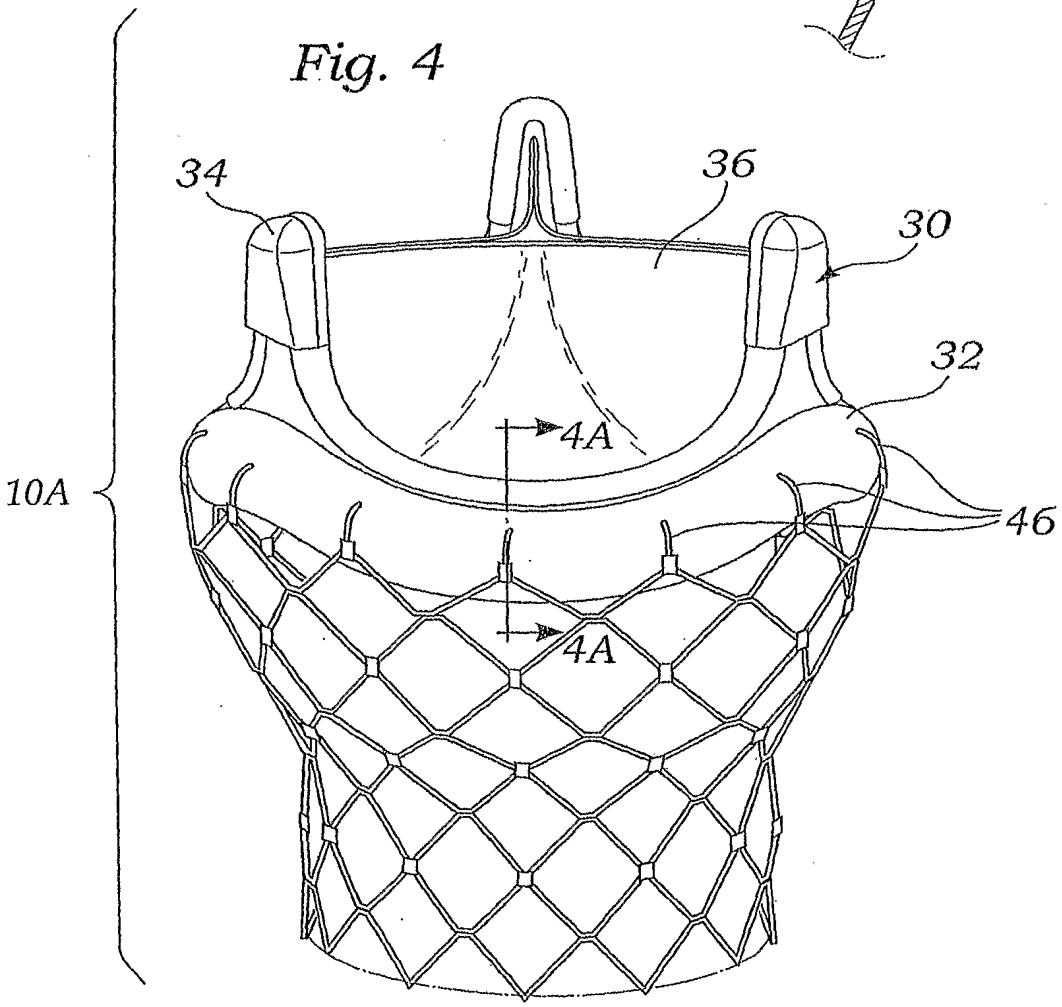


Fig.5A

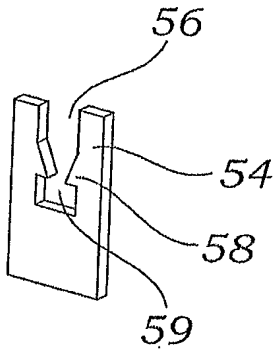


Fig.5

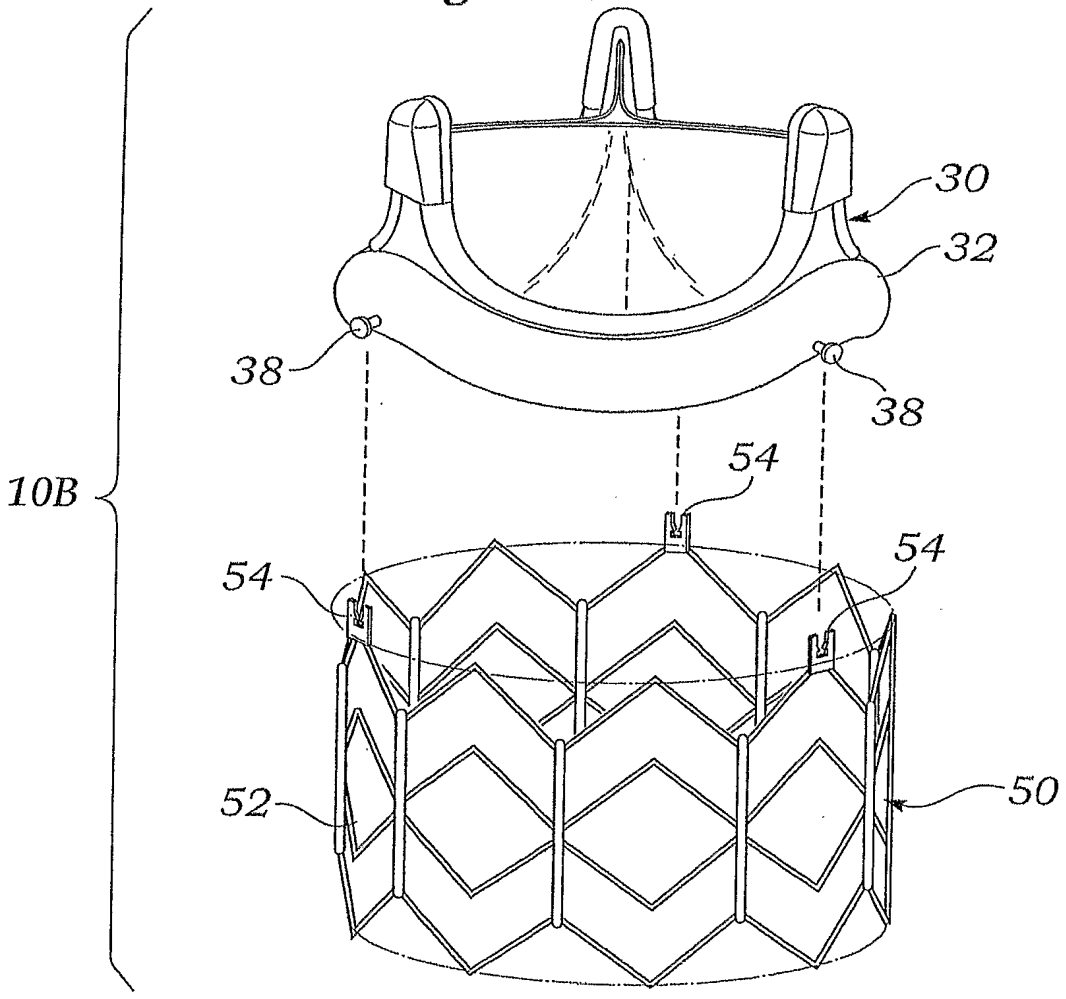


Fig. 6A

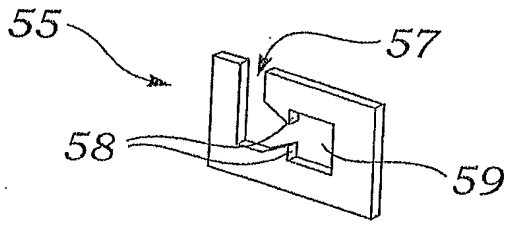


Fig. 6

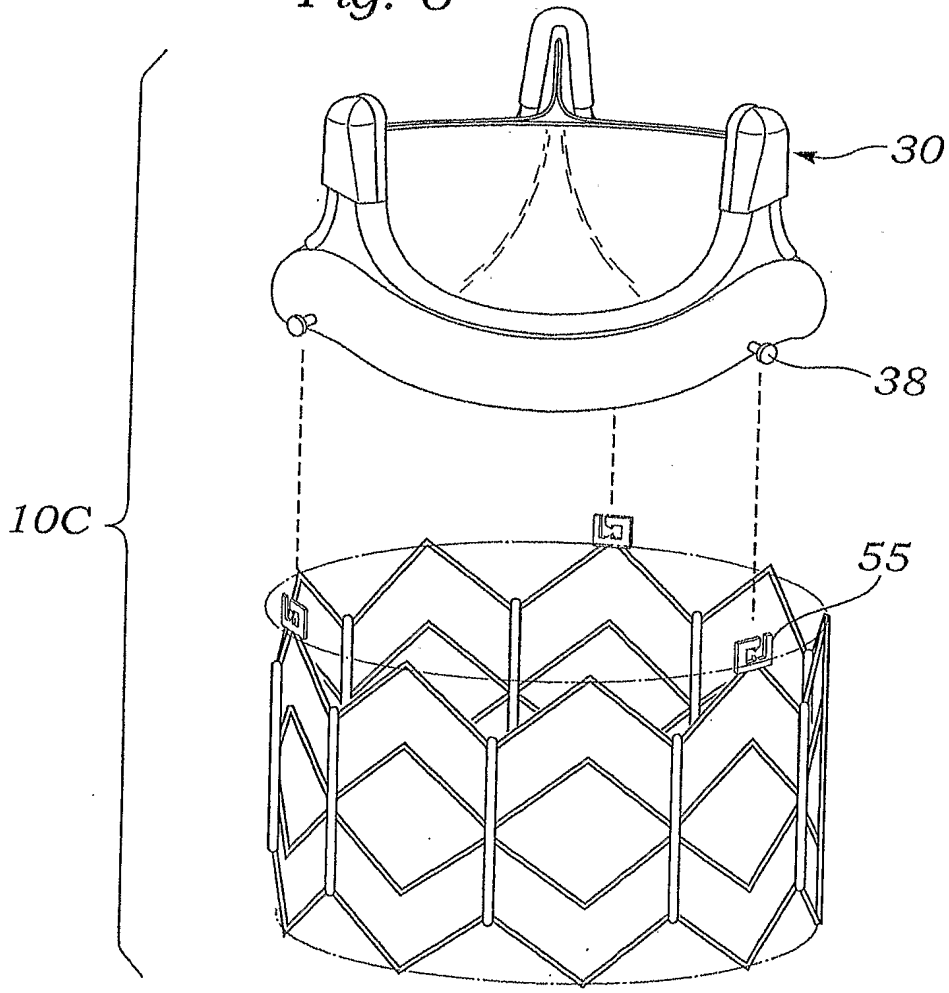


Fig. 7

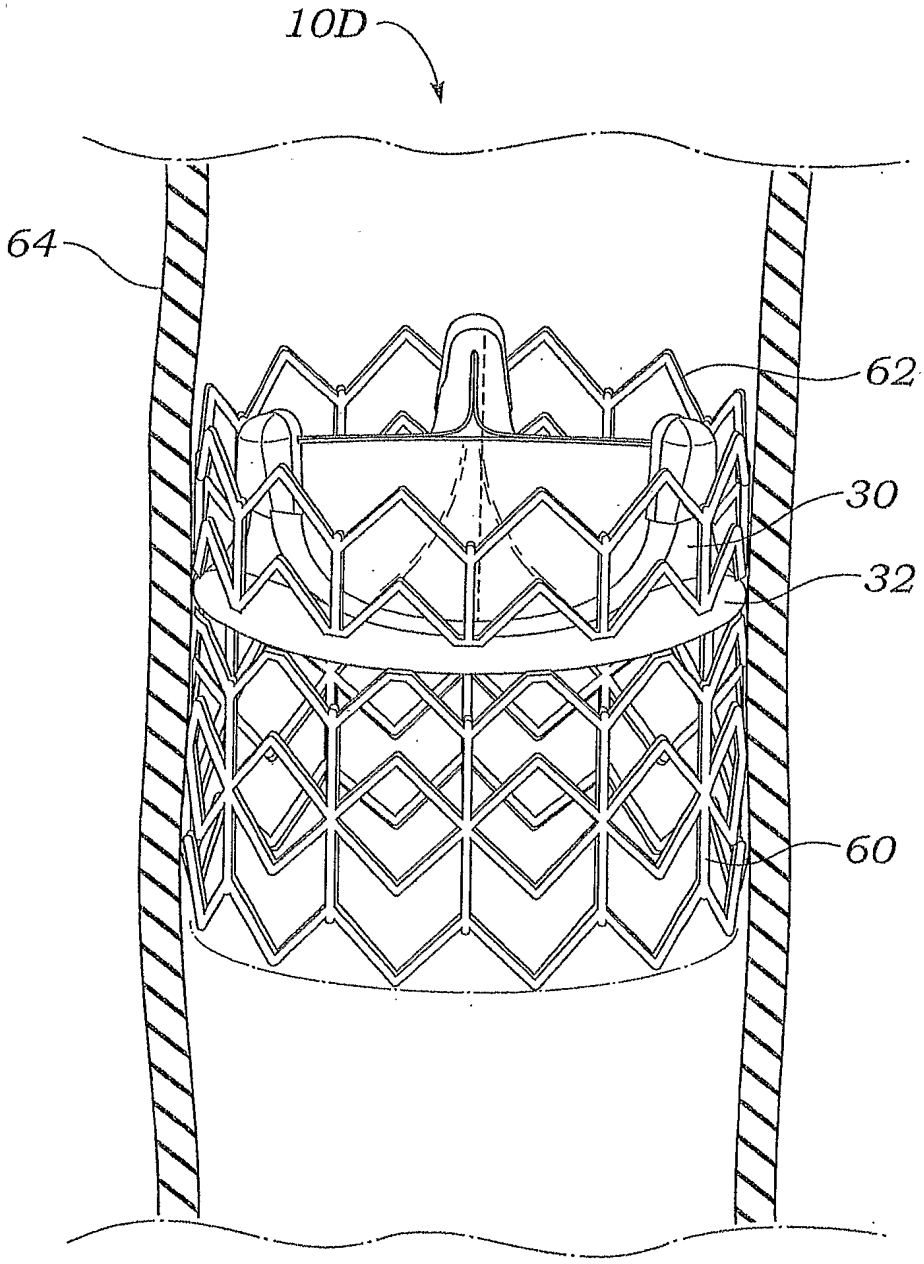
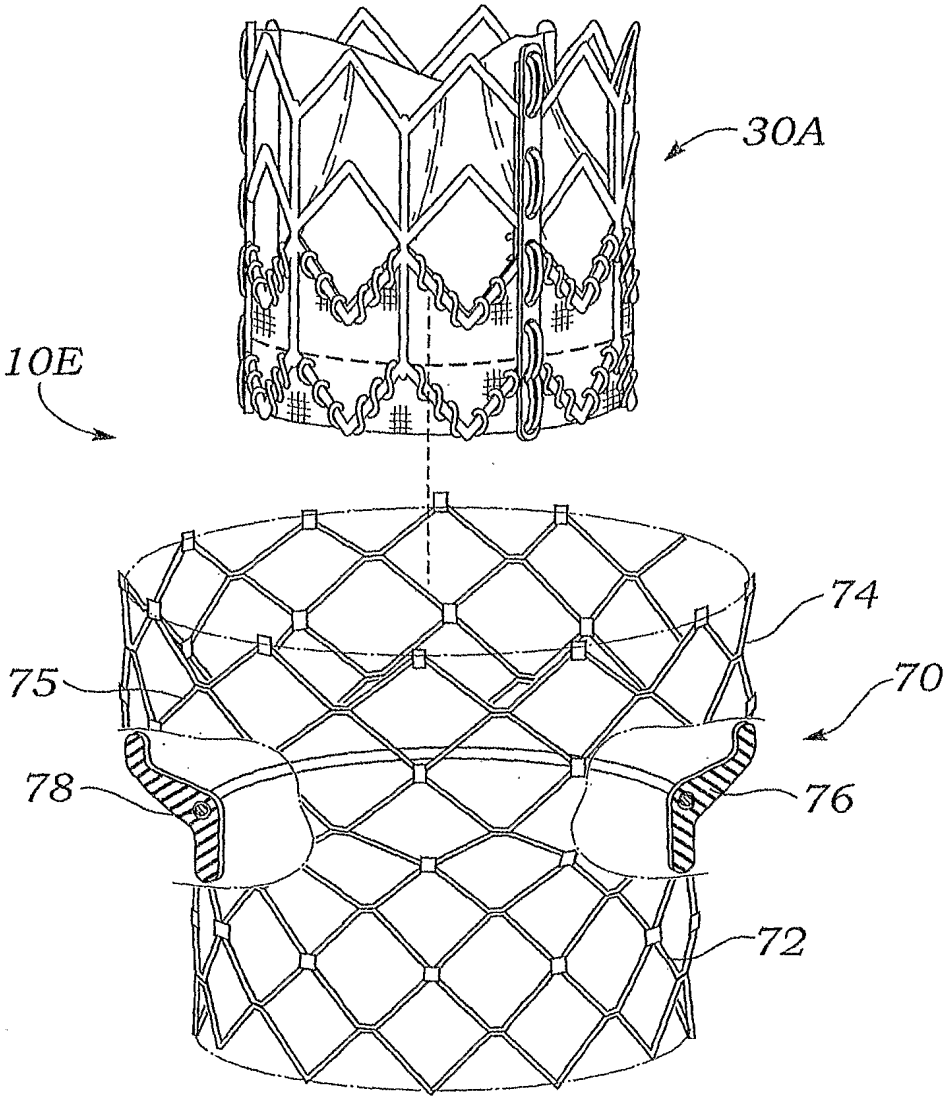


Fig.8



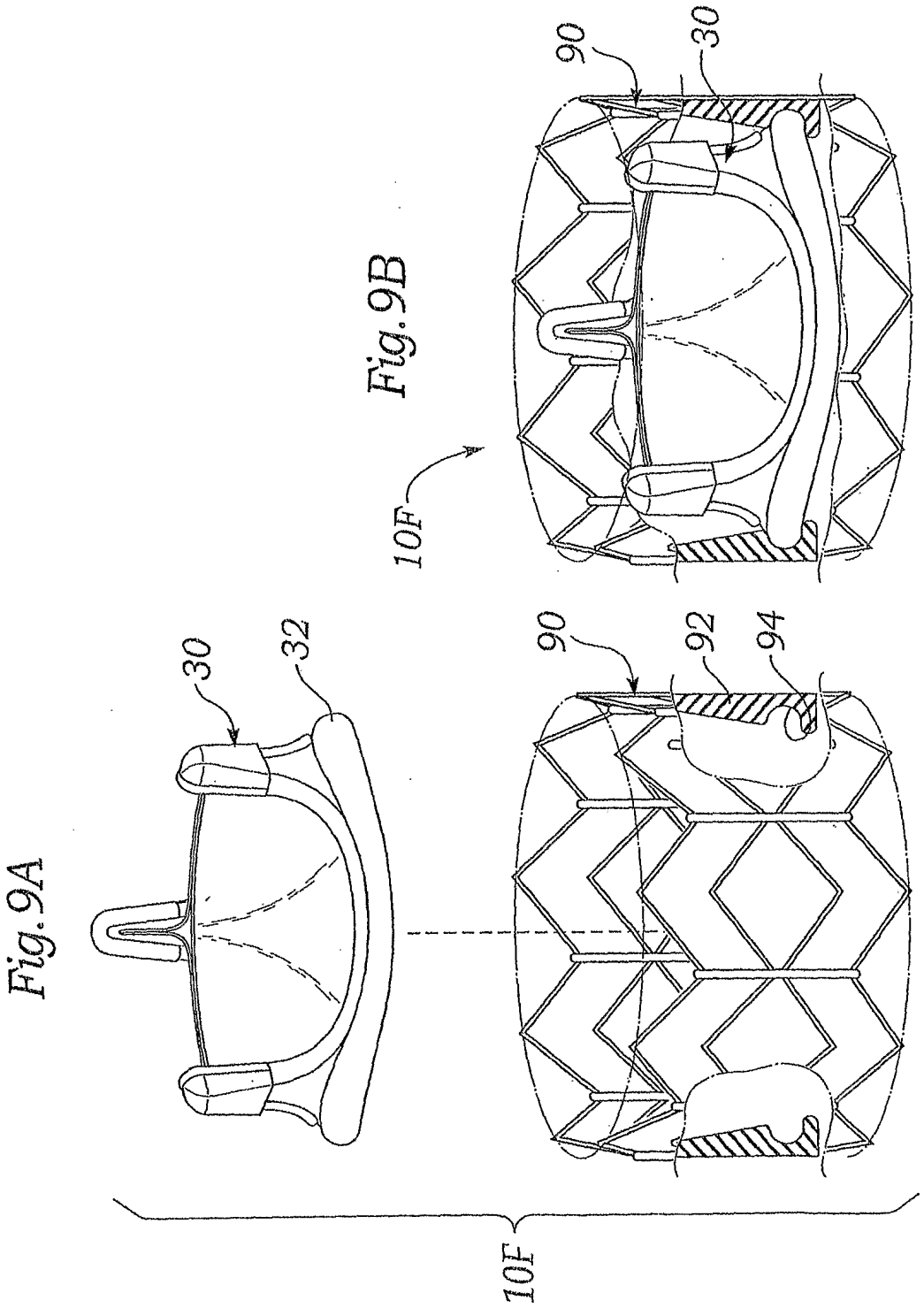


Fig. 9B

Fig. 9A

Fig. 10

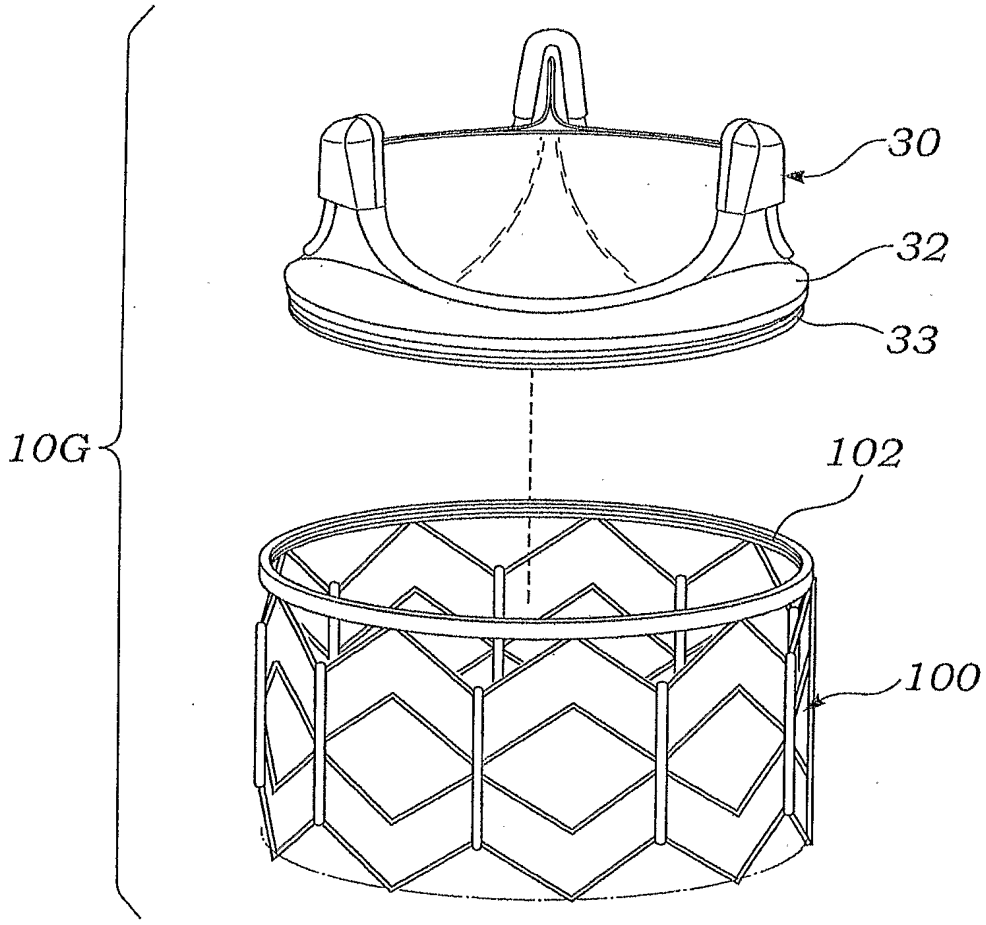
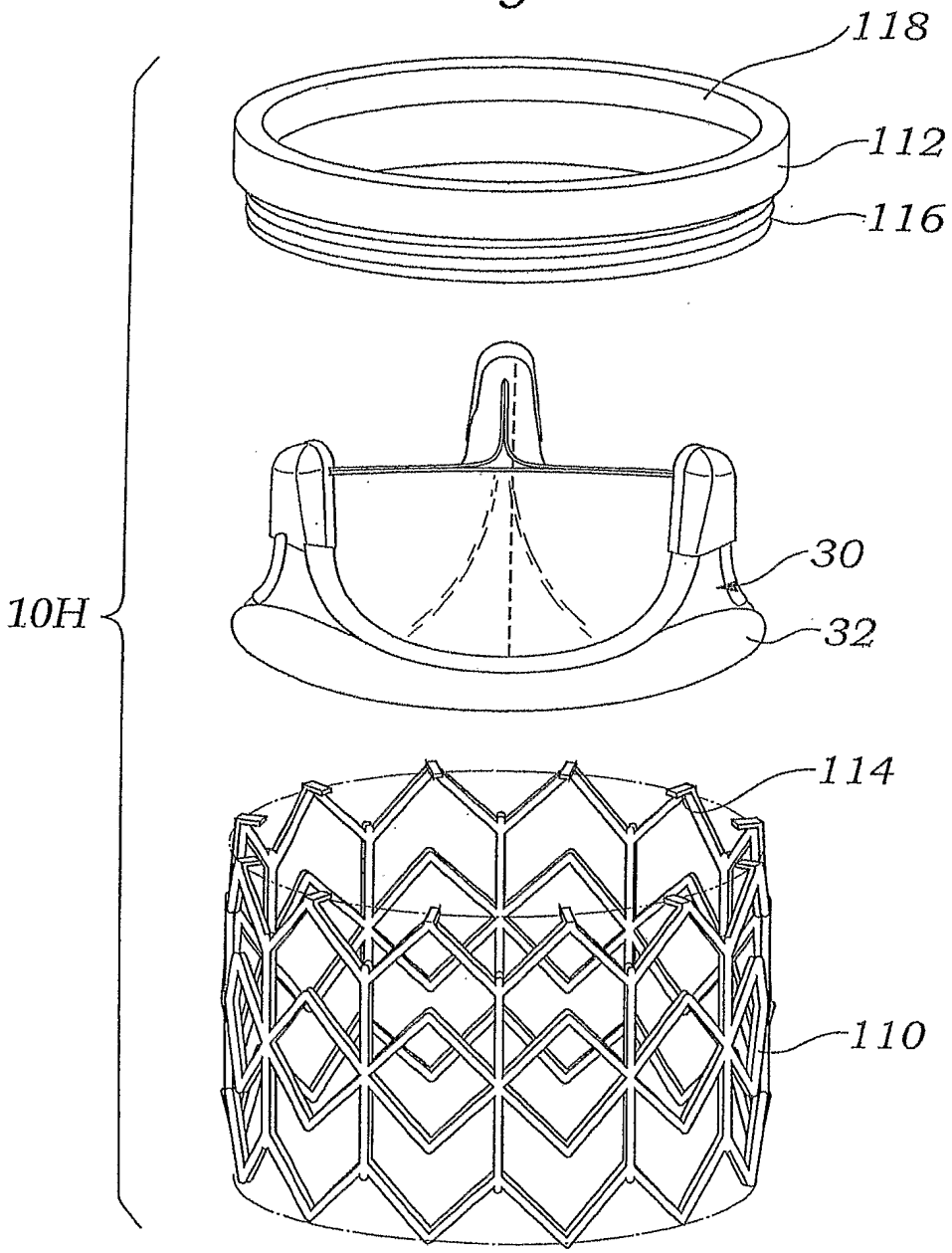
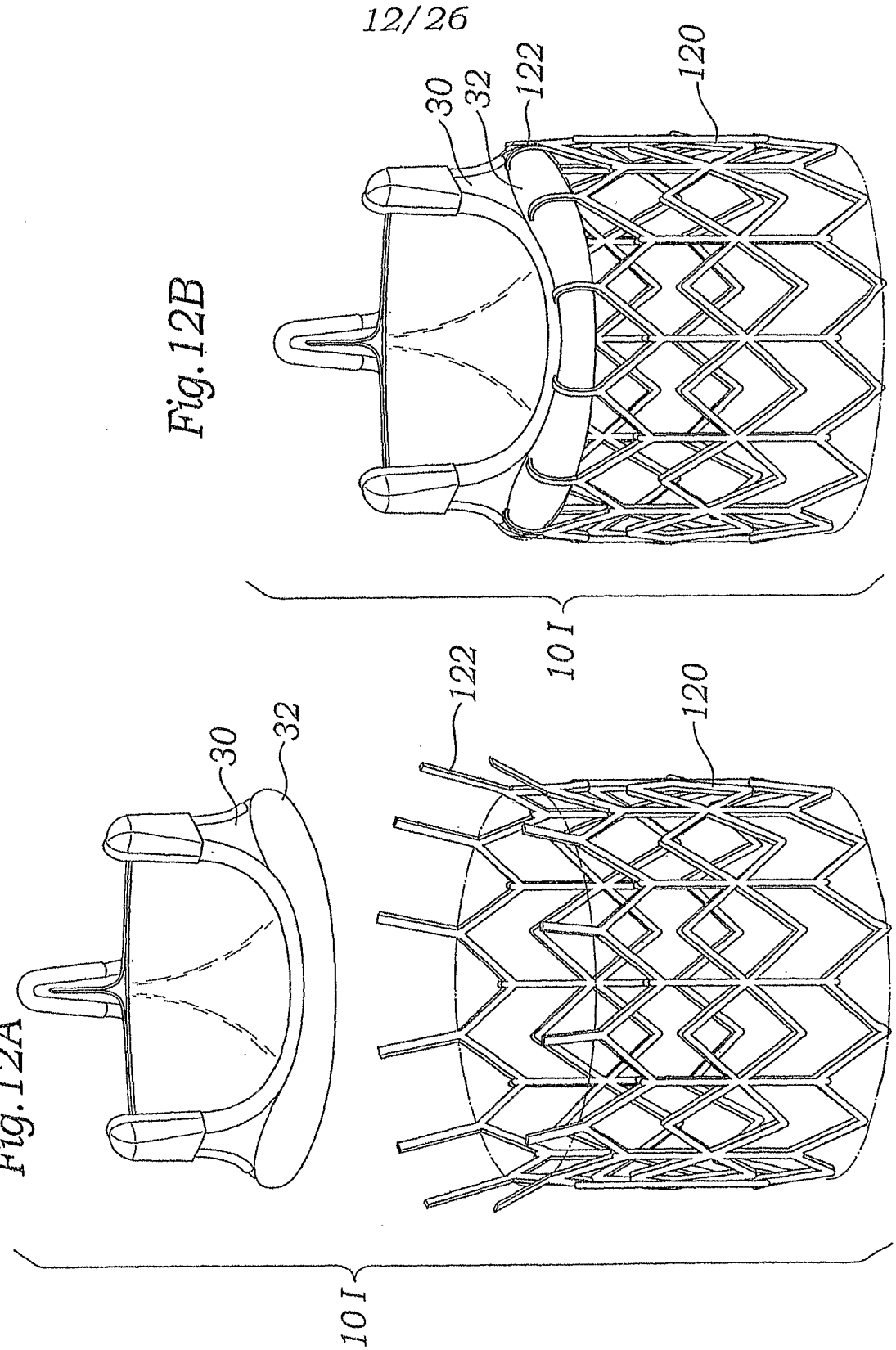


Fig. 11




30
32
122
120
101
Fig. 12B
30
32
122
120
101
Fig. 12A

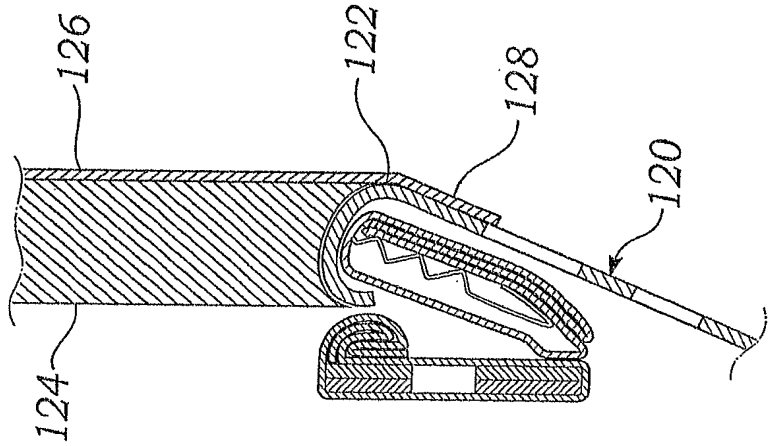


Fig. 12D

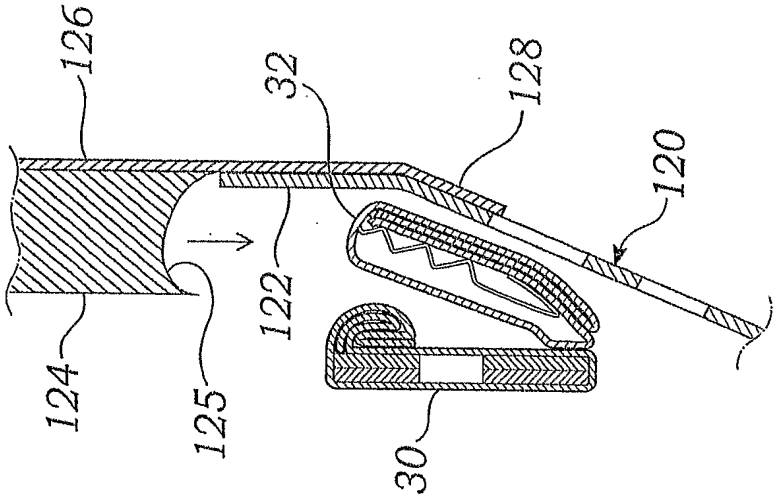


Fig. 12C

Fig. 13A

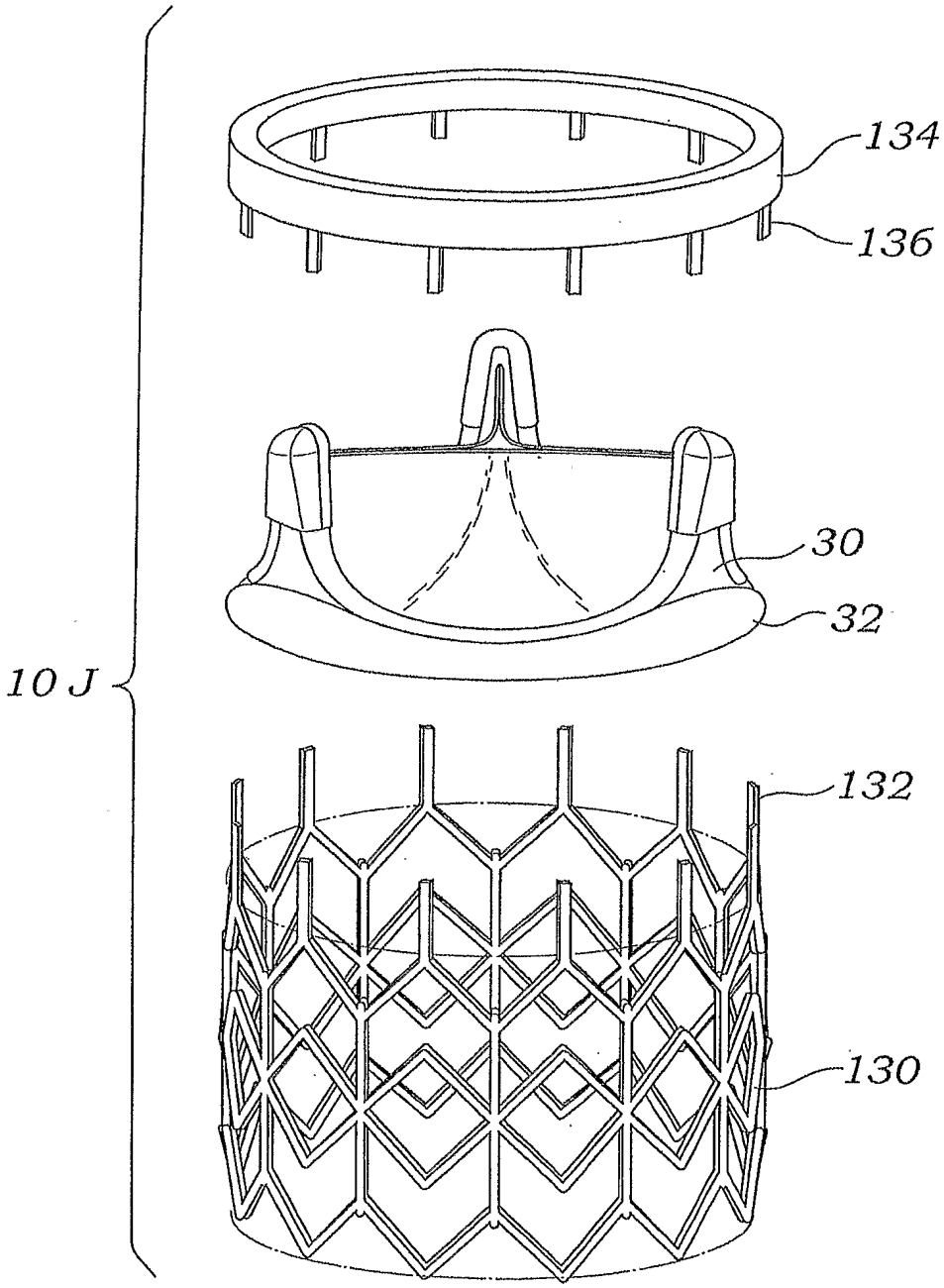


Fig. 13B

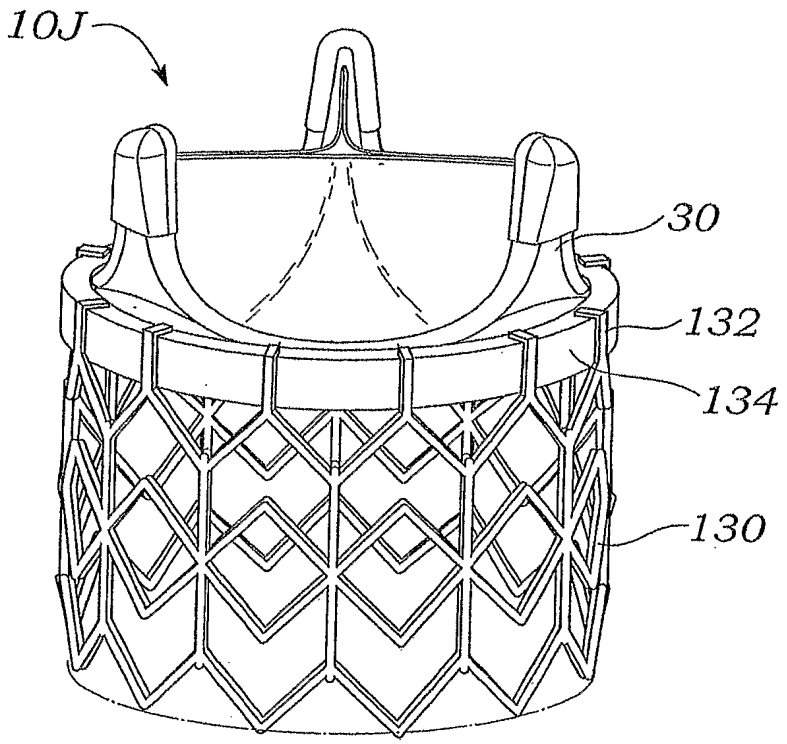


Fig. 14A

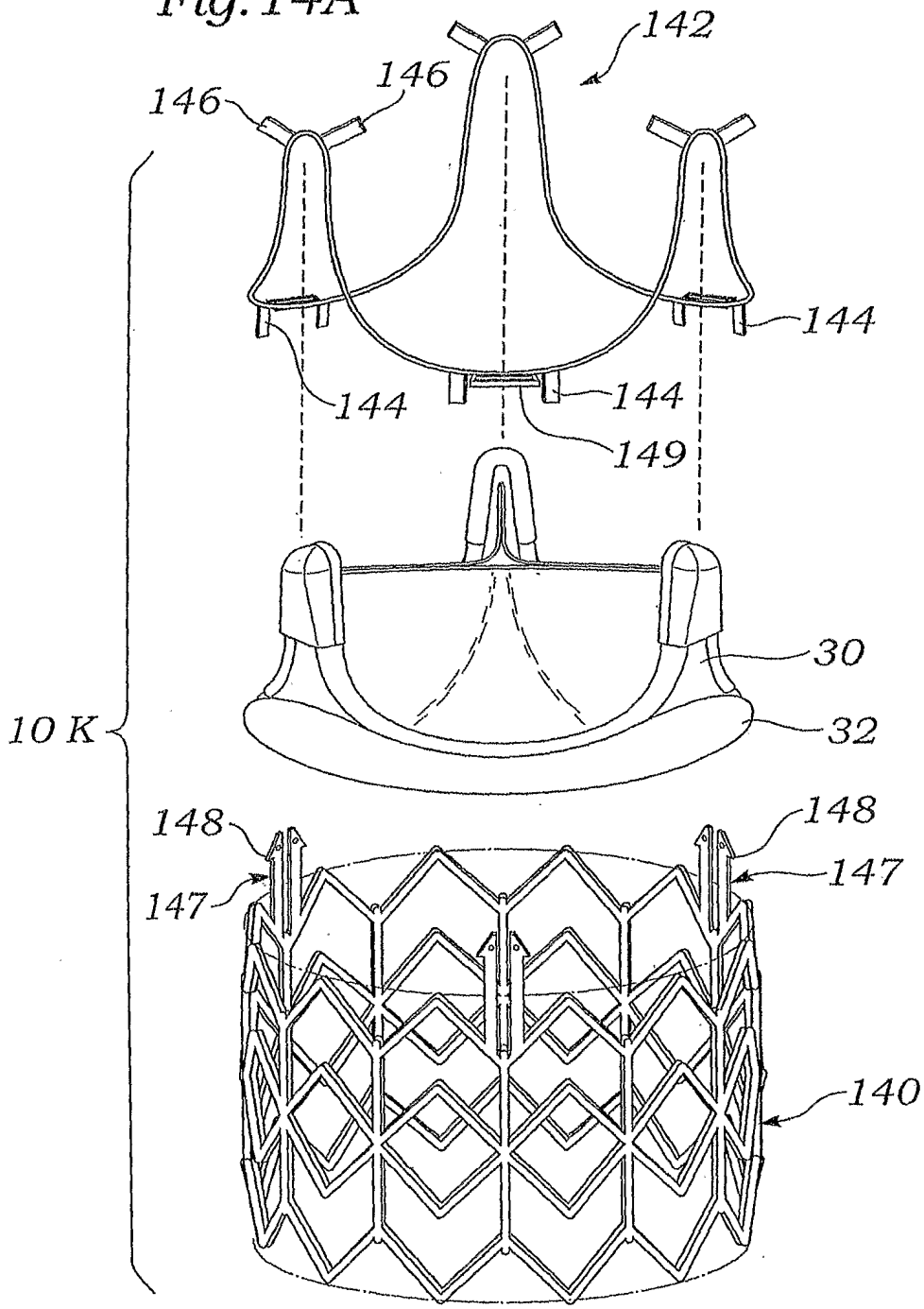
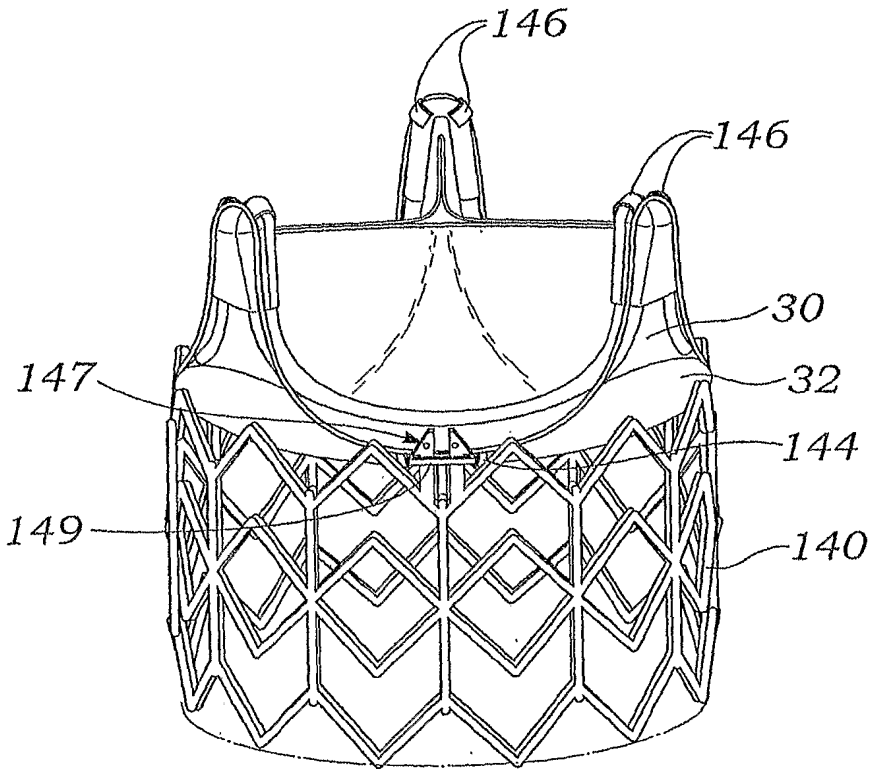


Fig. 14B



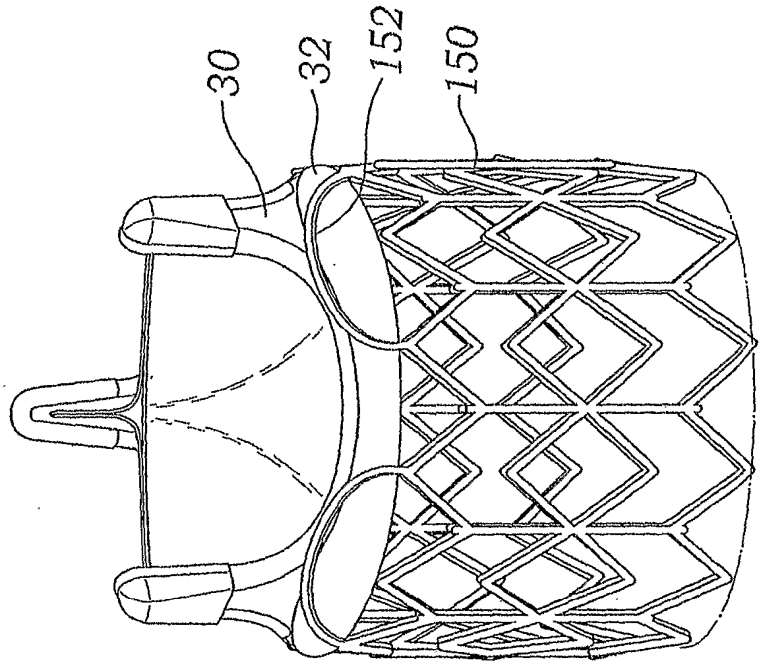


Fig. 15B

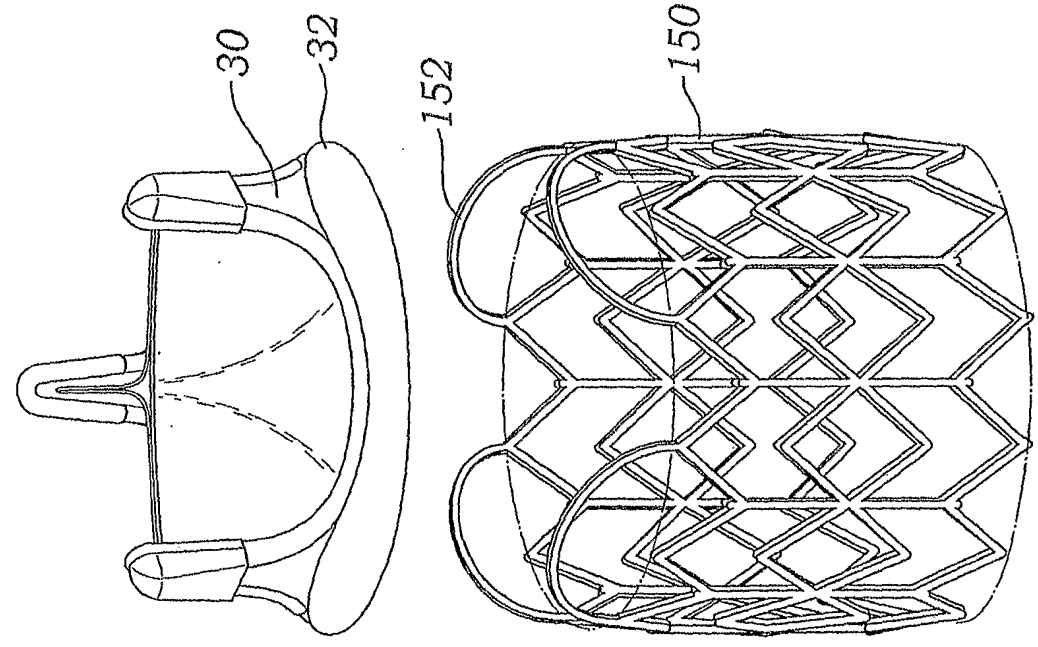


Fig. 15A

Fig. 16A

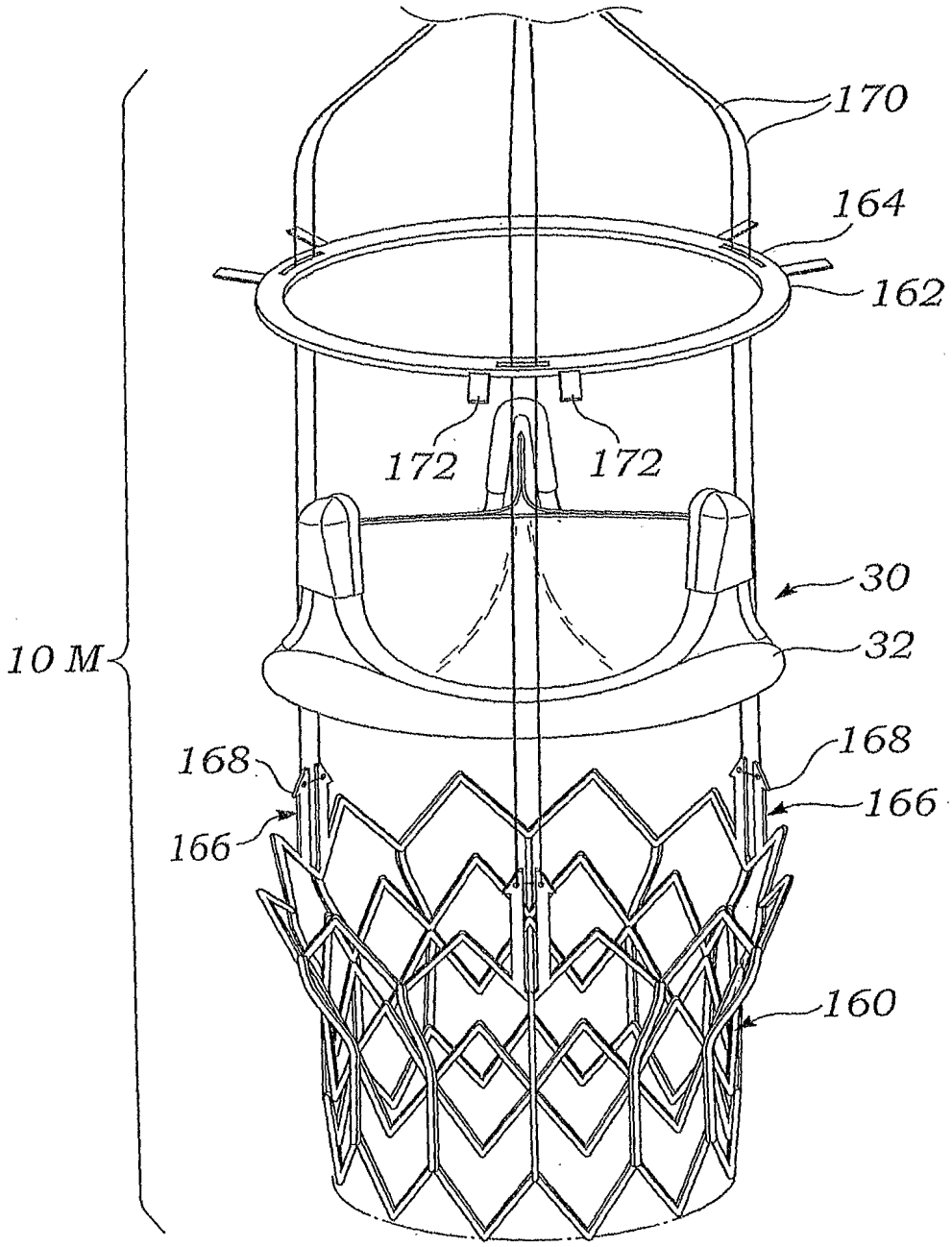


Fig. 16B

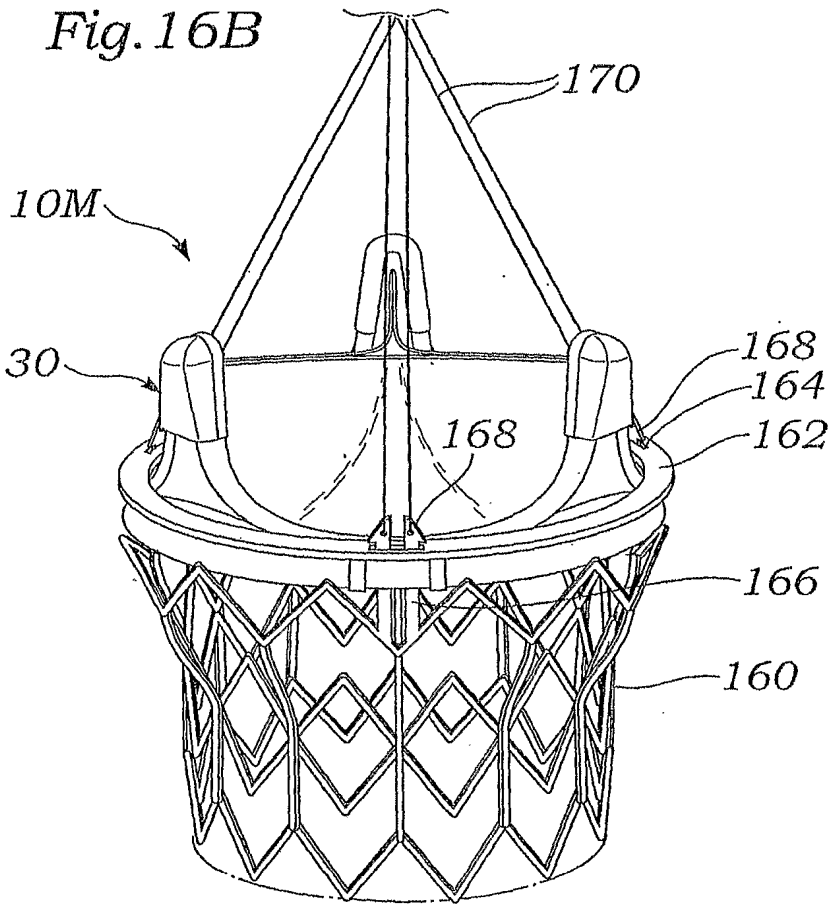


Fig. 17A

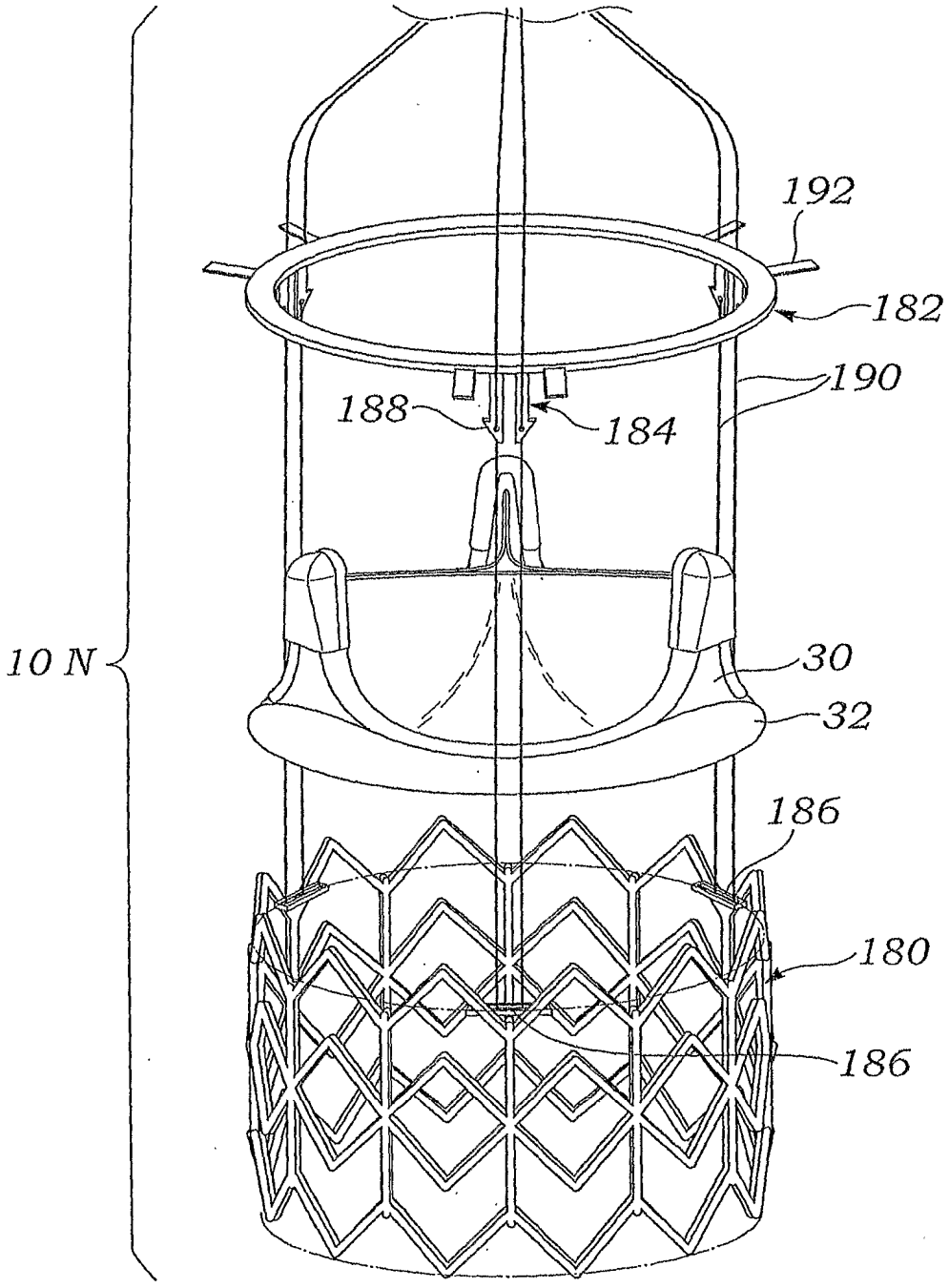


Fig. 17B

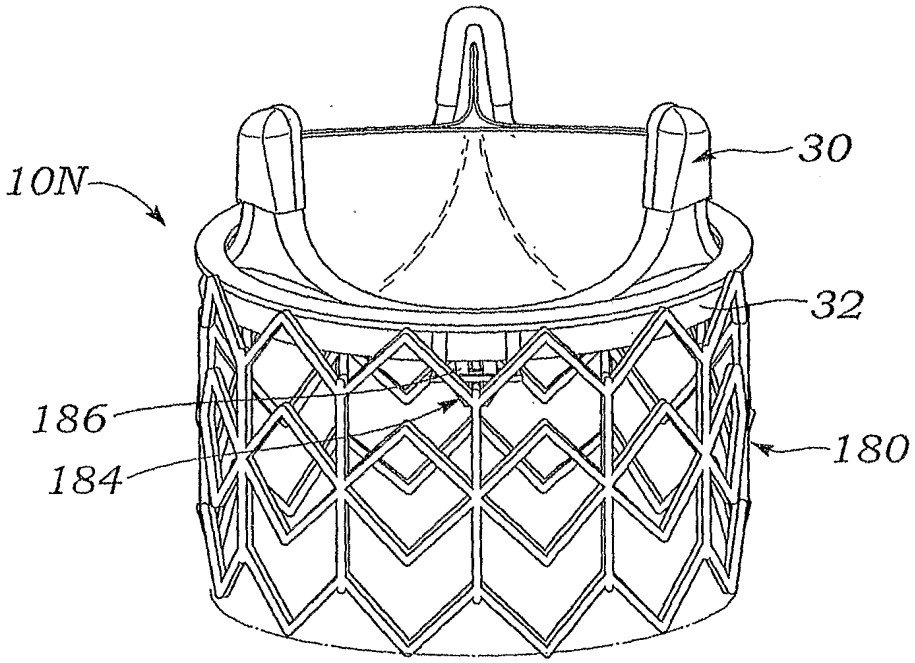


Fig.18

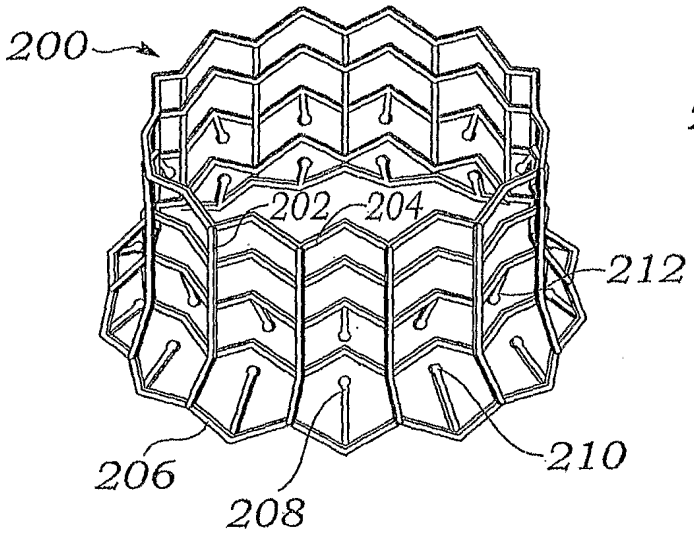


Fig.19

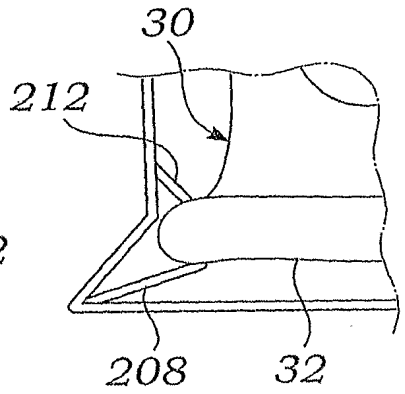


Fig.20

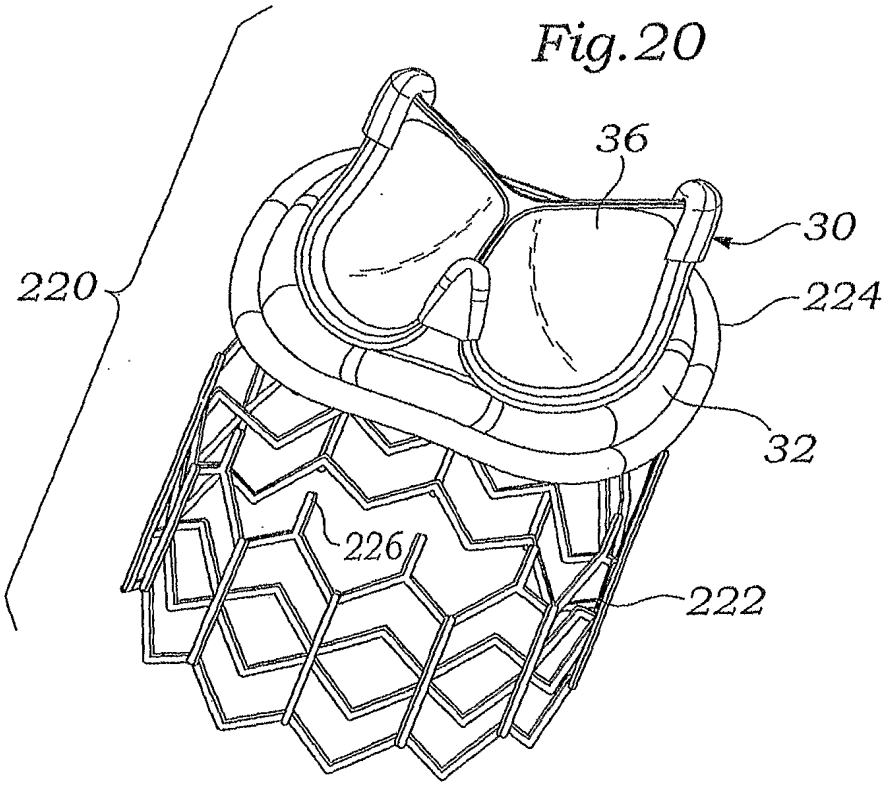


Fig. 21

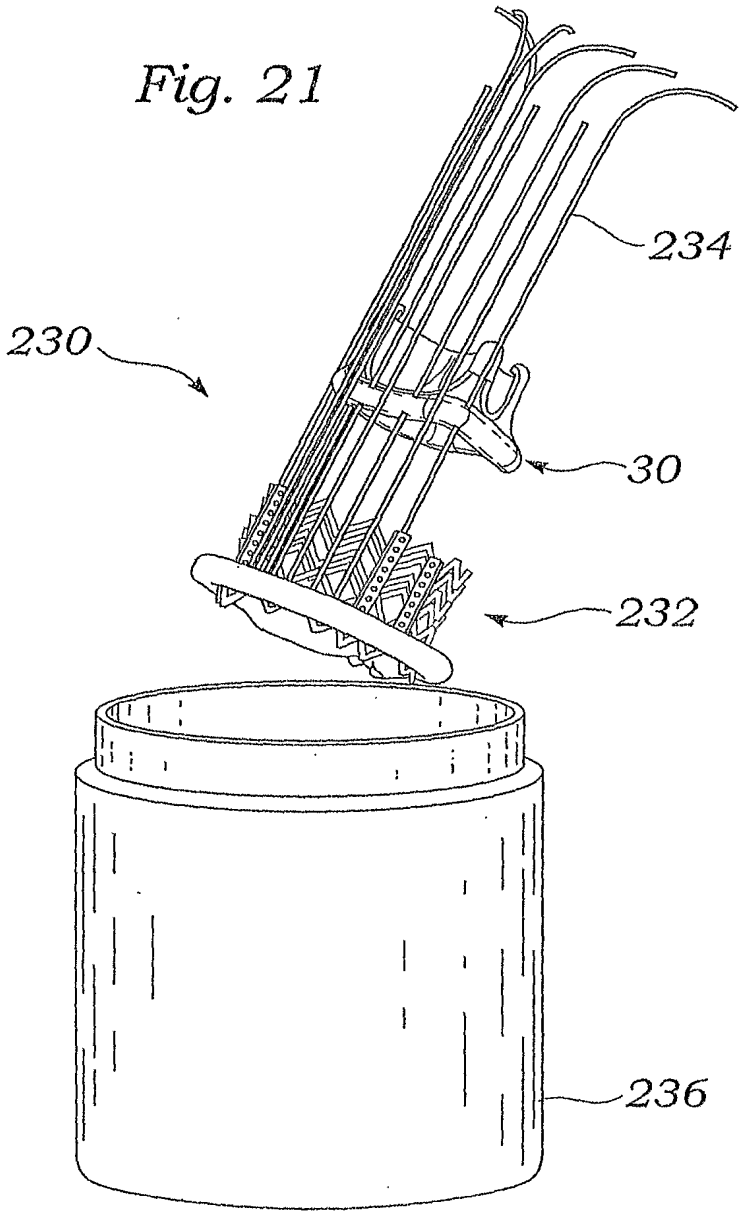


Fig. 22A

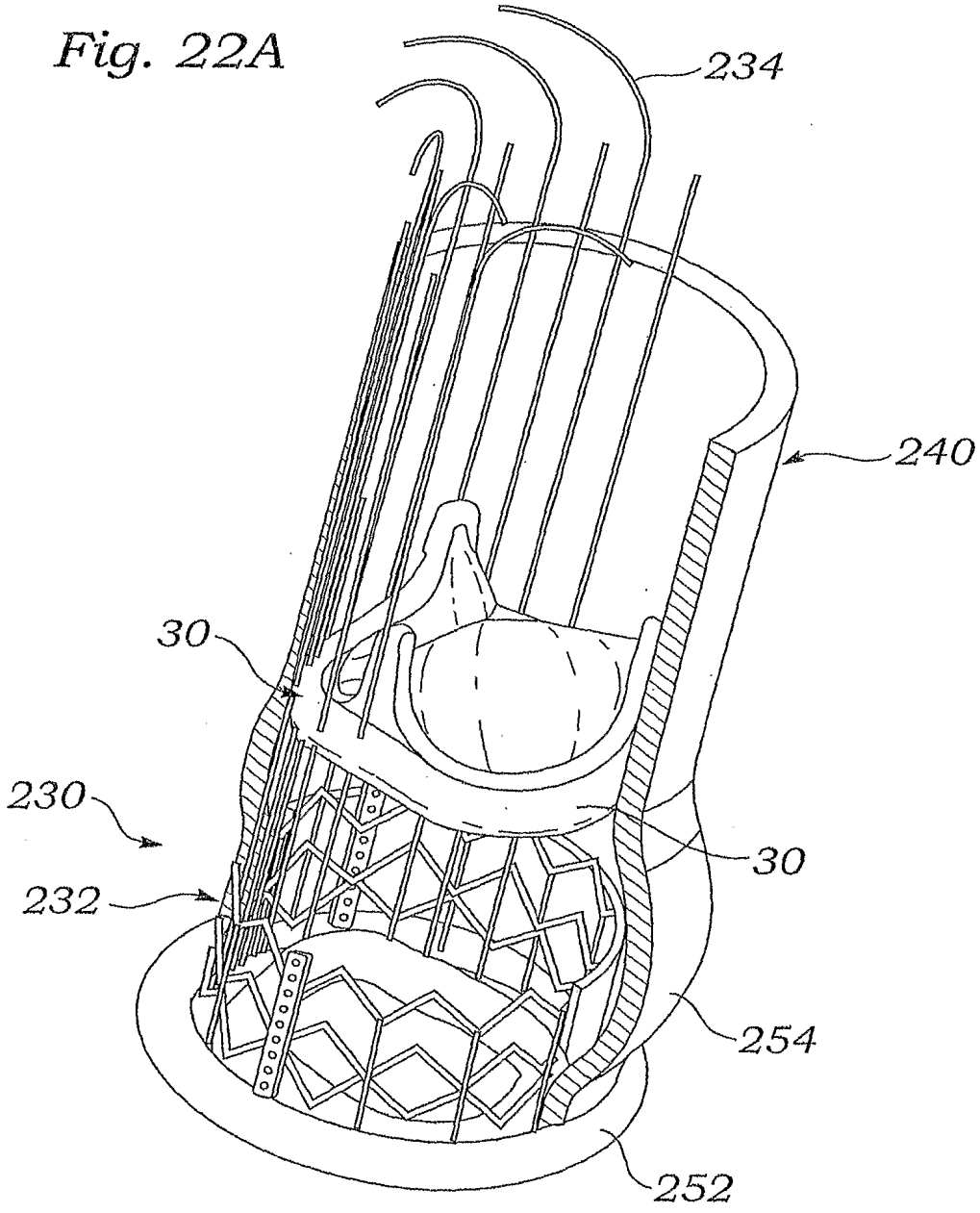


Fig. 22B

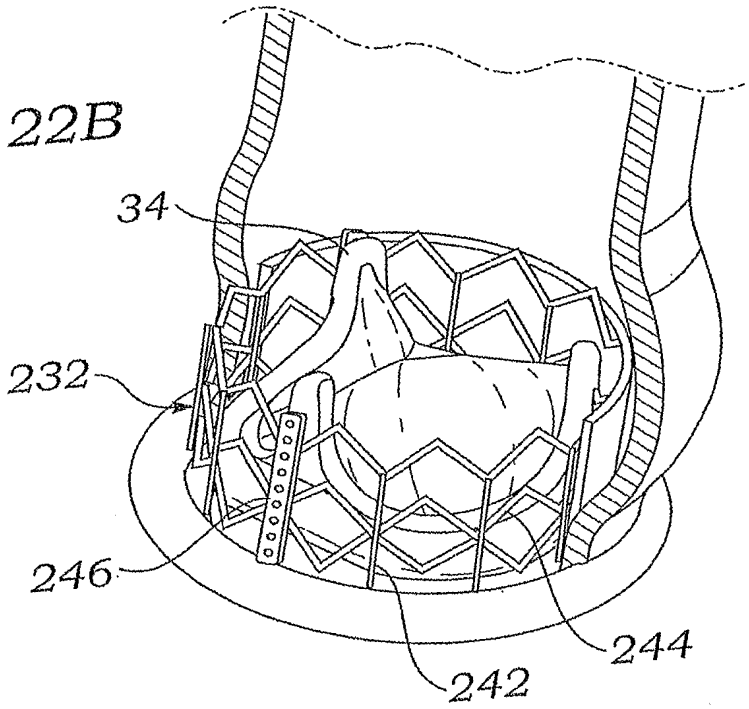
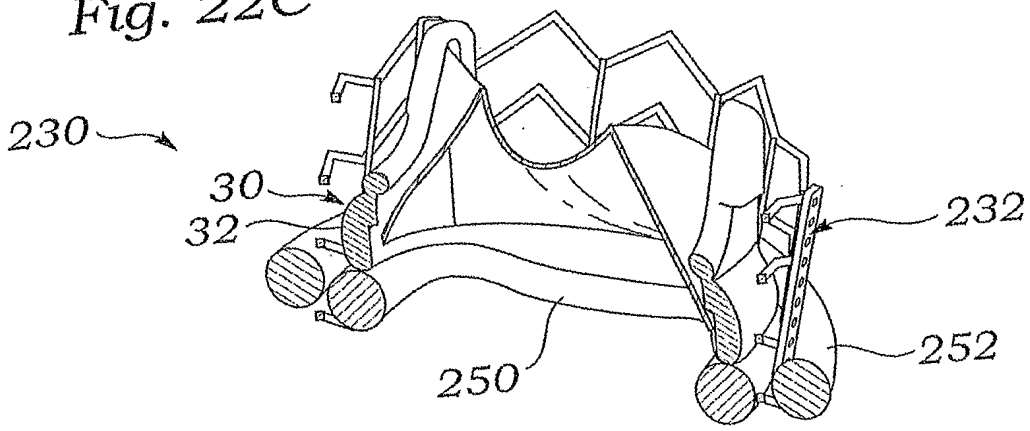


Fig. 22C



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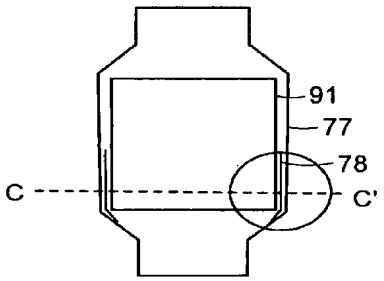
(54) Title: TRANSCATHETER HEART VALVE PROSTHESES



(57) Abstract: The present teachings relate to a heart valve prosthesis. The heart valve prosthesis includes a docking station (77) having a wire frame defining a lumen and a valve frame (91) for positioning within its lumen. The docking station includes a diaphragm (78) adapted to have an open position and a close position, which provides a temporary control mechanism for preventing free regurgitation during the time period between the deployment of the docking station and the deployment of the valve frame, and a sealing mechanism for preventing paravalvar leakage.

WO 2007/130537 A1

TRANSCATHETER HEART VALVE PROSTHESES

Technical Field

[0001] The present teachings relate generally to the treatment of heart valve dysfunction and, in particular, to minimally invasive systems and methods for replacing such heart valves.

Background

[0002] There are four valves within the human heart that serve to direct the flow of blood through the two sides of the heart in a forward direction. On the left (systemic) side of the heart are the mitral valve, located between the left atrium and the left ventricle, and the aortic valve, located between the left ventricle and the aorta. These two valves direct oxygenated blood coming from the lungs, through the left side of the heart, into the aorta for distribution to the body. On the right (pulmonary) side of the heart are the tricuspid valve, located between the right atrium and the right ventricle, and the pulmonary valve, located between the right ventricle and the pulmonary artery. These two valves direct de-oxygenated blood coming from the body, through the right side of the heart, into the pulmonary artery for distribution to the lungs, where it again becomes re-oxygenated to begin the circuit anew.

[0003] All four of these heart valves are passive structures that do not expend any energy themselves and do not perform any active contractile function. They consist of moveable leaflets that are designed simply to open and close in response to differential pressures on either side of the valve. The mitral and tricuspid valves are referred to as atrioventricular valves because of their location between an atrium and a ventricle on each side of the heart. The mitral valve has two leaflets and the tricuspid valve has three. The aortic and pulmonary valves are referred to as semilunar valves because of the unique appearance of their leaflets, which are more

aptly termed cusps and are shaped somewhat like a half-moon. The aortic and pulmonary valves each have three cusps.

[0004] The three cusps are soft tissue structures attached to a wall of the valve in an area designated as the annulus. In the case of the aortic valve, the three cusps are pushed open against the wall of the aorta during systole (when the left ventricle contracts), thereby allowing blood to flow through. During diastole (when the left ventricle relaxes), the left ventricular pressure falls and the aortic valve cusps reapproximate (the three cusps fall away from the wall and close), thereby preventing the blood which has entered the aorta from regurgitating (leaking) back into the left ventricle.

[0005] Heart valves may exhibit abnormal anatomy and function as a result of congenital or acquired valve disease. Problems with heart valve functions can be classified into two categories: 1) stenosis, in which a valve does not open properly, or 2) insufficiency (also called regurgitation), in which a valve does not close properly. Due to the higher-pressure gradient, the mitral and aortic valves are subject to greater fatigue and/or risk of disease. Also, while mitral valves often can be surgically repaired, most abnormalities of the aortic valve require replacement.

[0006] Prosthetic heart valves used to replace diseased or abnormal natural heart valves include mechanical devices with, for example, a rigid orifice ring and rigid hinged leaflets or ball-and-cage assemblies, and bioprosthetic devices that combine a mechanical assembly with biological material (e.g., human, porcine, bovine, or biopolymer leaflets).

[0007] In the past, heart valve replacement typically required median sternotomy and cardiopulmonary bypass. More recently, various prosthetic heart valves that can be implanted by less invasive procedures have been developed. For example, various replacement heart valve apparatus that can be delivered via an endovascular transcatheter approach are described in co-owned, co-pending U.S. Patent Application Serial Nos. 11/052,466 and 60/757,813, the entire disclosures of which are incorporated by reference herein for all purposes. The replacement heart valve apparatus described in these patent applications generally include a compressible

valve frame and a compressible docking station that is deployed prior to the introduction of the valve frame into a patient's heart. The valve frame is subsequently positioned within the docking station, which helps to support and anchor the valve frame in the desired location.

[0008] Like other transcatheter heart valves that are currently known or available, implantion of the aforementioned replacement heart valve apparatus in the aortic position (as opposed to the pulmonic position) presents unique challenges due to its close proximity to both the mitral valve and the coronary ostia, as well as high systemic pressures and the inability of the body to tolerate free leakage through the aortic valve for any period of time. For example, the implantation of the docking station in the aortic position can require coverage and complete immobilization of the native aortic valve, which will cause free regurgitation. Similar difficulties and challenges, albeit to a slighter extent, can be expected with implanting the replacement heart valve apparatus in other positions, for example, the mitral position, in which case, free regurgitation into the lungs via the left atrium can occur. Acute free regurgitation, even for the short period of time necessary to deliver the valve component within the docking station, is unlikely to be tolerated by the patient, particularly in the target population of patients with pre-existing heart conditions due to stenosis and/or regurgitation. While theoretically, a patient can be put on cardiopulmonary bypass to prevent or reduce such regurgitation, the various health risks associated with a bypass procedure make this an impractical option for many patients in the target population.

[0009] The present teachings, therefore, relate to an improved transcatheter heart valve prosthesis adapted to be implanted in the aortic position. However, the present teachings can be adapted for the replacement of other anatomical valves.

Summary

[0010] The present teachings solve the above-identified problem by providing transcatheter heart valve prostheses that can be delivered to and anchored in a patient's heart to replace or assist the function of a native heart valve. However, it should be understood that the present teachings also are applicable to replace a

replacement heart valve, e.g., one that has ceased functioning optimally. The present teachings also relate to methods of making and using the heart valve prostheses.

[0011] In one aspect, the present teachings relate to a heart valve prosthesis including a docking station that includes a wire frame defining a lumen and a replacement heart valve that includes a valve frame for positioning within the lumen of the docking station. The heart valve prosthesis also includes a diaphragm attached to the wire frame of the docking station and positioned within the lumen of the docking station. The diaphragm can be adapted to have an open position and a close position. The present teachings also recognize the docking station and the diaphragm as an independent and useful medical device. More specifically, the present teachings provide a medical device comprising a docking station comprising a wire frame defining a lumen, and a diaphragm positioned within the lumen and attached to the wire frame of the docking station, and can be adapted to have an open position and a closed position. It should be understood that the teachings herein in connection with the docking station and diaphragm of a heart valve prostheses apply equally to the medical device comprising a docking station and a diaphragm.

[0012] The docking station can define a generally cylindrical body that has a wall defining a lumen. The wall can include an outer surface (in contact with heart tissues when implanted) and an inner surface (in contact with blood flow when implanted), and the thickness of the wall can be constant throughout the length of the docking station or can be unevenly distributed between the outer surface and the inner surface. The docking station as a whole can include one or more portions with a substantially constant diameter (e.g., a cylindrical portion) and/or one or more portions with a varying diameter (e.g., a bulbous portion or a concave portion).

[0013] In some embodiments, the docking station can have an expanded position and a compressed position. The ability of the docking station to be compressed radially allows transcatheter delivery of the heart valve prosthesis. The docking station can be self-expandable or balloon-expandable. Depending on its intended implantation site, the docking station can include one or more openings such that its

implantation does not obstruct anatomical openings, for example, the coronary ostia. The docking station also can include radiopaque markers to allow visualization of the positioning of the docking station during its delivery and deployment. Visualization techniques such as fluoroscopy can be used. The radiopaque markers also can facilitate a medical practitioner to more precisely determine the diamater of the deployed docking station, which allows optimal sizing of the replacement heart valve.

[0014] The diaphragm attached to the docking station can help to prevent or reduce free regurgitation when the docking station is deployed at or near a native heart valve in a way that covers and/or immobilizes the native heart valve. The diaphragm can serve as a temporary control mechanism of blood flow prior to the introduction and deployment of the more permanent replacement heart valve. The diaphragm can open and close in response to differential pressures on either of its sides similar to the native heart valve and the replacement heart valve. In some embodiments, the diaphragm can function as a barrier that absorbs and/or restricts blood flow. Subsequent to the deployment of the replacement heart valve, the diaphragm can continue to function as a sealing mechanism that prevents paravalvar leakage.

[0015] In some embodiments, the diaphragm can be a unitary piece of material such as a membrane made of biological or synthetic materials. The membrane can include one or more slits that divide the membrane into multiple connected sections. In some embodiments, the diaphragm can include a plurality of leaflets. These leaflets can extend circumferentially along the diaphragm in an overlapping or non-overlapping configuration.

[0016] In some embodiments, the diaphragm can be directly attached to the wall of the docking station by sutures, adhesives, or other methods known in the art. In other embodiments, the diaphragm can be indirectly attached to the wall of the docking station, such as to a piece of material (e.g., a membrane) that itself is directly attached to the wall of the docking station. The diaphragm can be attached to any portion of the docking station within its lumen.

[0017] The valve frame of the replacement heart valve can include a substantially cylindrical body defining a lumen and a plurality of valve members attached to the substantially cylindrical body. In some embodiments, each of the valve members can include one or more curved wires and a leaflet. In certain embodiments, each of the valve members can include an inner curved wire support structure and an outer curved wire support structure. The leaflet of the valve member can include a leaflet body and one or more leaflet projections. In some embodiments, the one or more projections can be attached to a respective inner curved support structure and the leaflet body can extend over a respective outer curved support structure so as to position the leaflet body within the lumen of the valve frame of the replacement heart valve.

[0018] Another aspect of the present teachings relate to a method of delivering a heart valve prosthesis to an anatomical site. The method can include introducing a heart valve prosthesis of the present teachings into the heart through a catheter, deploying the docking station, and introducing a replacement heart valve into the lumen of the docking station through a catheter, and deploying the replacement heart valve within the lumen of the docking station so that the leaflets of the diaphragm are pressed between the wire frame of the docking station and the valve members of the replacement heart valve. The method can further include determining a diameter of the deployed docking station using fluoroscopy and choosing a replacement heart valve having a diameter that approximates the diameter of the deployed docking station.

[0019] These and other objects, along with the features of the present teachings herein disclosed, will become apparent through reference to the following description, the accompanying drawings, and the claims. Furthermore, it is to be understood that the features of the various embodiments described herein are not mutually exclusive and can exist in various combinations and permutations.

Brief Description of the Drawings

[0020] In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis generally being placed upon illustrating the principles of the present teachings.

[0021] FIGS. 1A and 1B illustrate an embodiment of an expanded docking station according to the present teachings.

[0022] FIGS. 2A-2D illustrate certain embodiments of an expanded docking station along with a diaphragm attached within its lumen according to the present teachings.

[0023] FIGS. 3A-3C illustrate the operation of various embodiments of a diaphragm and possible attachment configurations of such diaphragm within the lumen of a docking station according to the present teachings.

[0024] FIGS. 4A-4I illustrate nine different embodiments of a diaphragam according to the present teachings.

[0025] FIGS. 5A-5B show a top-view and a side view of an embodiment of a valve frame according to the present teachings.

[0026] FIGS. 6A and 6B are a top-view and a side-view of the valve frame of FIG. 5A located within the lumen of the docking station of FIG. 1A.

[0027] FIGS. 6C and 6D are a top-view and a cross-sectional view of the valve frame and docking station of FIGS. 6A and 6B with the members of the valve frame covered with a cover material and free ends of the cover material located away from the wall of the docking station.

[0028] FIGS. 6E and 6F are a top-view and a cross-sectional view of the valve frame and docking station of FIGS. 6C and 6D with the free ends of the cover material located towards the wall of the docking station.

[0029] FIG. 7 is a side view of an embodiment of a docking station and a valve frame (without leaflets) according to the present teachings.

[0030] FIG. 8 is an opened view of a portion of another embodiment of a valve frame (without leaflets) according to the present teachings.

[0031] FIG. 9 is a plan view of the embodiment of the valve frame of FIG. 7 with leaflets attached.

[0032] FIG. 10 is a plan view of an embodiment of a leaflet of a replacement heart valve.

[0033] FIG. 11 is a cross-sectional view through line AA' of FIG. 9 showing the attachment of the leaflet to the inner curved support structure and the placement of the leaflet over the outer curved support structure.

[0034] FIG. 12 is an opened view of a portion of yet another embodiment of a valve frame (without leaflets) according to the present teachings.

[0035] FIG. 13 is a plan view of the embodiment of the valve frame of FIG. 12 with leaflets attached.

[0036] FIG. 14 is a cross-sectional view through BB' of FIG. 13 showing the attachment of the leaflet to the inner curved support structure and the placement of the leaflet over and between the outer curved support structure.

[0037] FIG. 15 is an opened view of a portion of another embodiment of a valve frame (without leaflets) of the invention.

[0038] FIGS. 16A-16D illustrate an embodiment of implanting a heart valve prosthesis according to the present teachings.

[0039] FIG. 17A is a schematic drawing showing the side view of an embodiment of a transcatheter heart valve prosthesis according to the present teachings.

[0040] FIG. 17B is a cross-sectional view of the transcatheter heart valve prosthesis of FIG. 17A along the line C-C'.

[0041] FIG. 17C is an expanded view of the circled portion of FIG. 17A.

[0042] FIG. 18A is a schematic drawing showing the side view of an embodiment of a transcatheter heart valve prosthesis according to the present teachings.

[0043] FIG. 18B is an expanded view of the circled portion of FIG. 18A.

[0044] FIGS. 19A-C illustrate how a diaphragm according to the present teachings can seal potential space between the docking station and the replacement heart valve, thereby preventing paravalvar leakage.

Detailed Description

[0045] The present teachings relate to a heart valve prosthesis that mitigates the potential complications of free regurgitation that may occur during the implantation of a replacement heart valve. Specifically, the present teachings relate to a modification of an existing replacement heart valve apparatus that includes a supporting structure and a replacement heart valve. The supporting structure, such as a docking station, a stent or a scaffold, is adapted to be deployed at a preselected position within an anatomical lumen of the heart via an introducing catheter. The phrase "docking station" is herein used to broadly refer to all types of supporting structures including stents. The replacement heart valve is then inserted into the deployed docking station using the same catheter or, alternatively, a second catheter, and deployed within the lumen of the the docking station. A person skilled in the art will recognize that while many features of the replacement heart valve apparatus of the present teachings are adapted for transcatheter delivery, the replacement heart valve apparatus can be implanted via other methods, for example, via various surgical techniques including those in which the delivery catheter and/or the replacement heart valve apparatus can be implanted through a direct incision in or a puncture of, for example, the left ventricle (e.g., for implanting a replacement aortic valve or a replacement mitral valve) or the aorta (e.g., for implanting a replacement

aortic valve). Accordingly, embodiments related to transcatheter delivery described herein are to be considered as only illustrative and not restrictive.

[0046] While the two-component replacement heart valve apparatus of the present teachings enables the use of smaller catheters because the inner diameter of the catheter need not accommodate, at the same point in time of the procedure, the compressed volume of both a docking station and a valve assembly, the two-part deployment procedure introduces a certain lag time between the deployment of the docking station and the valve assembly. The lag time can be problematic when the docking station needs to be deployed in the same luminal space as the native heart valve. Specifically, the native valve will be forced open by the deployed docking station, which leads to a period of free regurgitation until the introduction and deployment of the valve assembly. Such acute free regurgitation can lead to various clinical complications that are unlikely to be tolerated by patients requiring a heart valve replacement.

[0047] To prevent regurgitation, the present teachings provide a modified heart valve prosthesis in which the docking station is provided with a diaphragm. The diaphragm has an open position and a close position similar to the native heart valve and the replacement heart valve in that it can open and close in response to differential pressures on either of its sides. For example, in embodiments where the replacement heart valve prosthesis is placed in the aortic position, blood can still flow out of the left ventricle during ventricular systole, but free regurgitation is prevented, or at least reduced, during diastole because of the presence of this temporary barrier. Similarly, in embodiments where the replacement heart valve prosthesis is placed in the mitral position, the diaphragm can open to allow blood flow during ventricular diastole and atrial systole, but back flow is prevented or reduced during ventricular systole. The patient's heart, therefore, is afforded a stabilizing period before the more permanent replacement heart valve is implanted. Different embodiments of the docking station, the diaphragm, and the replacement heart valve will be described in more detail hereinbelow.

[0048] Throughout the description, where compositions are described as having, including, or comprising specific components, or where processes are described as having, including, or comprising specific process steps, it is contemplated that compositions of the present teachings also consist essentially of, or consist of, the recited components, and that the processes of the present teachings also consist essentially of, or consist of, the recited processing steps.

[0049] In the application, where an element or component is said to be included in and/or selected from a list of recited elements or components, it should be understood that the element or component can be any one of the recited elements or components and can be selected from a group consisting of two or more of the recited elements or components.

[0050] The use of the singular herein includes the plural (and vice versa) unless specifically stated otherwise. In addition, where the use of the term "about" is before a quantitative value, the present teachings also include the specific quantitative value itself, unless specifically stated otherwise.

[0051] It should be understood that the order of steps or order for performing certain actions is immaterial so long as the present teachings remain operable. Moreover, two or more steps or actions can be conducted simultaneously.

[0052] The docking station of the heart valve prosthesis according to the present teachings can be a self-expandable or a balloon-expandable stent that can be compressed radially to a desirable French size. In some embodiments, the docking station can be dimensioned to fit in a catheter having a diameter no larger than about 22 Fr (7.3 mm). For example, the docking station can have a diameter of about 5 mm or less when crimped. When expanded, the widest portion of the docking station can have a diameter of about 30 mm, and the narrowest portion can have a diameter of about 25 mm.

[0053] As shown in FIGS. 1A and 1B, one embodiment of a docking station 30 according to the present teachings can define a generally cylindrical body that has a wall 34 defining a lumen 36. The wall can include an outer surface (in contact with

heart tissues when implanted) and an inner surface (in contact with blood flow when implanted), and the thickness of the wall can be constant throughout the length of the docking station or can be unevenly distributed between the outer surface and the inner surface. The docking station 30, both longitudinally and in terms of its cross-section, can define various shapes and can be made to approximate or be compatible with the anatomical site where it is intended to be implanted. For example, in some embodiments, the cross-section of the docking station can be circular, elliptical, or define other eccentric shapes. In some embodiments, the docking station as a whole can be, without limitation, generally, substantially, or somewhat cylindrical, conical, spherical, barrel-like, or hourglass-like. By way of illustration, for a docking station adapted to be implanted in the aortic position, its general shape can be tubular with a relatively long major axis (i.e., parallel to the direction of blood flow), while a docking station adapted to be implanted in the mitral position can be concave in shape and relatively short in its major axis to accommodate the geometry of the mitral annulus and to avoid interference with the blood flow into the left ventricle.

[0054] To further illustrate, the geometry of the docking station can resemble, without limitation, one of the four embodiments illustrated in FIGS. 2A-D.

[0055] Referring to FIG. 2A, in some embodiments, the docking station can include a first cylindrical portion at one end and a second cylindrical portion at the other end, and an intermediate portion therebetween, where the intermediate portion also can be cylindrical but have a larger diameter than the first cylindrical portion and the second cylindrical portion. There also can be a tapered portion extending from each of the first cylindrical portion and the second cylindrical portion to the intermediate portion as shown in FIG. 2A.

[0056] FIG. 2B shows another embodiment of a docking station. The docking station can have a first cylindrical portion and a second cylindrical portion similar to the embodiment shown in FIG. 2A. The intermediate portion, however, can be of a bulbous or barrel shape that again has a greater diameter than the first and second cylindrical portions.

[0057] Other embodiments of the docking station are illustrated in FIGS. 2C and 2D. Referring to FIG. 2D, the docking station can have a relatively short major axis and a relatively wide diameter. And unlike FIGS. 1B, 2A and 2B all of which show a docking station with a wider intermediate portion, the docking station can include terminal portions that are wider than the intermediate portion, for example, similar to the shape of an hourglass, as shown in FIG. 2D. Also, the wall of the docking station can have varying thickness as shown in FIG. 2D. For example, the wider terminal portions can be a thicker wall compared to the narrower intermediate portion. A docking station having a shape that resembles the docking station shown in FIG. 2D can be well-adapted for placement in the mitral position. Its external contour, for example, can conform to the space between the left ventricle and the left atrium, while its internal contour can allow the stable positioning of the valve frame to be placed therein. In some embodiments, the terminal portions (e.g., the first cylindrical portion and the second cylindrical portion in FIGS. 2A and 2B) of the docking station can have the same or a different diameter, and can be absent in some embodiments as shown in FIG. 2C.

[0058] In some embodiments, the docking station can be made of a slotted tube or a series of interconnected wires that together form an expandable mesh or wire frame. In addition to the interstices of the mesh, the wire frame can include additional larger openings that represent openings native to the implantation site. For example, if the implantation site is at or near the aortic valve, the docking station can include one or more openings to allow fluid communication with the coronary ostia.

[0059] The docking station can be made of various materials that are compatible with placement in the body, that possess desirable material wear properties and/or that have a minimal risk of causing infection in the body of the patient. Examples of suitable materials include shape memory materials, stainless steel alloys, molybdenum alloys, pyrolitic carbon, and certain polymers. For example, the wire frame can be constructed from strips of a shape memory material. By way of example, the shape memory material can be nickel-titanium wire sold under the product name nitinol. The nickel-titanium wire, when properly manufactured,

exhibits elastic properties that allow the wire to be manipulated (e.g., bent) by an operator and then returned to, substantially, the same shape the wire possessed prior to it being manipulated. The wire can return to substantially its original shape when the operator heats the wire or, alternatively, when the operator removes the forces applied to bend the wire.

[0060] Other than the French size advantage mentioned above, the two-component replacement heart valve apparatus also affords the additional benefit of allowing optimal sizing of the replacement heart valve to be implanted. After deployment, the docking station, whether self-expandable or balloon-expandable, can have a final diameter that is slightly different than what is originally anticipated, as tissue compliance cannot always be accurately predicted. When the docking station and the replacement heart valve are delivered in a one-step procedure, the replacement heart valve may turn out to be too big or too small. When the replacement heart valve is too big, leaflet redundancy results, which in turn can lead to premature degeneration of the leaflets. When the replacement heart valve is too small, it may not properly anchor within the docking station and can become embolic. A two-component system provides the medical practitioner an opportunity to determine the final diameter of the deployed docking station and select a replacement heart valve of an optimal dimension. Accordingly, in some embodiments, the docking station can include one or more radiopaque markers or other visualization means to allow visual determination of its deployed dimension.

[0061] To allow the docking station to be implanted in the same luminal space as the native valve and to prevent free regurgitation, the docking station can include a diaphragm. Referring to FIGS. 3A-C, the diaphragm 38 is adapted to open and close in response to differential pressures on either of its sides. FIG. 3A shows an implanted docking station in which the diaphragm 38 is in the close position and provides a barrier to the back flow of blood (in the direction of the arrow). FIGS. 3B and 3C show an implanted docking station in which the diaphragm 38 is in the open position, allowing blood to flow through the docking station.

[0062] The diaphragm can be attached to the docking station by various means, for example, by suturing, adhesives, welding, crimping, insert molding, and the like. The diaphragm can be attached at various positions within the lumen of the docking station. For example, and as shown in FIGS. 3B and 3C, the diaphragm 38 can be attached within the intermediate portion of the docking station, within the tapered portion of the docking station, or within one of the terminal portions of the docking station (not shown). By way of further example, and for application in the aortic position, the diaphragm can be attached just below the openings (provided for the coronary ostia) of the docking station.

[0063] Referring to FIGS. 4A-4I, the diaphragm 38 can be a unitary piece of material or can include a plurality of leaflets 39. With continued reference to FIGS. 4A-4I, the diaphragm 38 can optionally include one or more slits (FIGS. 4A, 4C, 4F and 4G) and/or perforations (FIGS. 4B, 4D, 4E and 4G). For example, and referring to FIG. 4F, the membrane 38 can include two perpendicular slits, giving rise to four sections or leaflets 39. The slits can converge at the center of the diaphragm or at some other point on the diaphragm, and provide an opening for blood to flow through. The diaphragm can have one or more perforations in place of or in addition to the slit(s). The diaphragm can also include an outer reinforcement ring 37 (FIGS. 4G-4I) that can help secure the diaphragm to the docking station and provide enhanced structural integrity to the diaphragm. In some embodiments, the diaphragm can include a plurality of leaflets. The leaflets can extend circumferentially and can be overlapping or non-overlapping. For example, as shown in FIGS. 4A-4C and 4E-4I, the diaphragm can include two, three, four, five or more leaflets. Referring to FIGS. 4B and 4C, the leaflets can have a substantially triangular shape, the tips of which can converge at the concentric point of the diaphragm. In some embodiments and referring to FIGS. 4H and 4I, the leaflets can be substantially semicircular, and can be of the same size or different sizes. As shown in FIGS. 4B, 4D and 4E, the diaphragm can include a perforation or opening in the center of the diaphragm, off-center (not shown), or extending partially along its diameter. In other embodiments (not shown), the leaflets of the diaphragm can be in a curved or spiral-like overlapping configuration, resembling an iris diaphragm

found in a camera. Other designs and configurations are within the scope of the present teachings.

[0064] The diaphragm can be made of various biocompatible materials. The diaphragm can be made of a biological membrane (e.g., human, ovine, porcine, bovine valve leaflets, pericardium, intestinal lining, or covering tissue, etc.), a bio-engineered material, or a synthetic material (e.g., polymers such as polyethylene, PTFE). In some embodiments, the biological or synthetic material or membrane can be supported by wires made of, for example, nitinol. The diaphragm also can be a wire mesh including flexible metallic struts made of nitinol or other metals or alloys.

[0065] Because the diaphragm is designed to function for a limited period of time (the time between the deployment of the docking station and the deployment of the valve assembly can be as short as less than a minute to as long as a few days), the mechanical requirements of the diaphragm are much less demanding than a typical replacement heart valve. For example, the materials used to make the diaphragm can be thinner and have less structural integrity than a more permanent replacement heart valve, which helps to retain the French size advantage of the original two-component replacement heart valve system. In certain embodiments, the diaphragm, in addition to or instead of providing an open and close position, can act as a barrier that can help control the extent of regurgitation by absorbing a certain amount of blood or slowing down blood flow. In these embodiments, the diaphragm can be made of an absorbing material such as various polymeric foams.

[0066] Replacement heart valves that can be used in connection with the aforedescribed docking station and diaphragm include various transcathether replacement heart valves known in the art. For example, and referring to FIGS. 5A and 5B, the replacement heart valve can include a valve frame 40 made of a shape memory material. The valve frame 40 can define a generally cylindrical body that is constructed from a mesh 42. The mesh 42 can be constructed from wires or strips of a shape memory material. The valve frame 40 also can have three valve members 44a, 44b and 44c. The valve members 44a, 44b and 44c can have a free end 48a, 48b and 48c, respectively. The valve frame 40 could, alternatively, be any geometric shape (e.g., cylindrical, conical, spherical or barrel-like) that is compatible

with the placement of the valve frame 40 within a docking station, such as the docking station 30 of FIG. 1B.

[0067] As shown in FIGS. 6A and 6B, the valve frame 40 can be deployed within the lumen 36 of the docking station 30. The valve frame 40 and the docking station 30 are hereinbelow referred to as the valve assembly 50 collectively. The valve frame 40 can be manufactured to ensure that the valve frame 40 can maintain a desired (e.g., fixed) placement with respect to the docking station 30 when the valve frame 40 and the docking station 30 are located within the heart of a patient and subjected to the flow of blood through the valve assembly 50.

[0068] Referring now to FIGS. 6C and 6D, the valve members 44a, 44b and 44c can be coated, typically, with a cover material 56 (e.g., a biocompatible material, such as, silicon rubber or bovine, porcine or human tissue that is chemically treated to minimize the likelihood of rejection by the patient's immune system). The coated valve members can be capable of functioning similarly to the three cusps of the aortic valve, for example. The cover material can be a bio-engineered material that is capable of being applied to the valve members. The cover material can be applied to the valve frame prior to deployment of the valve frame into the body. Again referring to FIGS. 6C and 6D, the cover material 56 can have three free ends 46a, 46b and 46c corresponding to valve members 44a, 44b and 44c, respectively. The free ends also are herein referred to as leaflets.

[0069] With continued reference to FIGS. 6C and 6D, after placement of the valve frame within the docking station (located within the body), the cover material 56 applied to the valve members 44a, 44b and 44c is capable of, generally, obstructing the flow of blood in the negative direction along the X-axis. The free ends 46a, 46b and 46c move away from the inner wall 34 of the docking station 30, thereby limiting the flow of blood in the negative direction along the X-axis. However, referring now to FIGS. 6E and 6F, as blood flows in the positive direction along the X-axis, the free ends 46a, 46b and 46c of the cover material 56 move towards the inner wall 34 of the docking station 30. The free ends 46a, 46b and 46c, thereby permit the flow of blood through the valve assembly 50. In this manner, the

valve assembly approximates the functioning of a natural heart valve of the body by allowing blood to flow in the positive direction along the X-axis.

[0070] FIG. 7 shows another embodiment of a valve frame that can be used with the docking station and diaphragm described above. The valve frame 340 includes a substantially cylindrical body portion 341, a plurality of valve attachment pairs 346, and a plurality of standoffs 350 attached to one or more exterior serpentine wire rings 353. In some embodiments, and as shown in FIG. 12, the plurality of standoffs 350 and the one or more exterior serpentine wire rings 353 are absent.

[0071] As shown, the substantially cylindrical body portion 341 of the valve frame 340 can be constructed of a plurality of serpentine curved wires 352. Each of the vertices 356 of the serpentine curves of a first wire 352 can be attached at the vertices 356 to each of the vertices of the serpentine curves of an adjacent wire 352. In one embodiment, the wires can be constructed of nitinol. Again the substantially cylindrical body portion 341 can be expandable between a first compressed state (not shown) and a second expanded state (shown). It should be noted that when the terms "vertex" or "trough" are used, the convention is that the term "trough" is a bend in the wire that points in the direction of blood flow (i.e., in the positive direction of X shown in FIG. 8) and a "vertex" is a bend that points in a direction opposite blood flow (i.e., in the negative direction of X shown in FIG. 8.

[0072] At one end of the cylindrical body 341 of the valve frame 340 are three sets of valve attachment pairs 346 for attaching valve leaflets 390. Each valve attachment pair 346 can incude an inner curved support structure 358 and an outer curved support structure 360. Each curved support structure 358, 360 can be attached either to a vertex 362, 364 (respectively as shown in FIG. 7) or to a trough 372 and vertex 370 (respectively as shown in FIG. 8). In some embodiments (as shown in FIGS. 8 and 15), the space S between the inner curved support structure 358 and the outer curved support structure 360 can be constant. The space S, for example, can be in the range of about 2-3 mm. The inner curved support structure 358 and the outer curved support structure 360, as well as the space S therebetween, can be substantially parabolic in shape (as shown in FIG. 8) or can resemble a pocket, i.e., a partial rectangle with rounded corners (as shown in FIG. 12).

[0073] By placing the attachment of the outer 360 and inner 358 curved support structures to the body 341 of the valve frame 340, at adjacent vertices 370 and troughs 372, the distance between the inner 358 and outer 360 curved support structures can be substantially assured. As a result, the movement of the valve leaflets 390 does not cause the curved support structures 358, 360 to touch, thereby preventing damage to the leaflets 390.

[0074] In some embodiments, the inner curved support structure 358 and the outer curved support structure 360 can each include one piece of wire only (shown in FIG. 8). In other embodiments, the inner curved support structure 358 can have one piece of wire, while the outer curved support structure 360 can have two or more pieces of wire (shown in FIG. 12). It is preferred that the two or more pieces of wire of the outer curved support structure 360 are spaced as closely as possible but still permit passage of the chosen cover material 396 (shown in FIGS. 13 and 14). For example, the cover material can have a thickness of 0.4 mm to about 1.0 mm, and the space between the wires of the outer curved support structure can be within the range of about 0.5 mm to about 1.0 mm.

[0075] More details of the leaflet 390 are shown in FIG. 10. With reference to FIGS. 9, 10, 11, 13 and 14, a leaflet 390 can attached to each valve attachment pair 346. Each leaflet 390 has a leaflet body 396 and a plurality of leaflet projections 392. When attached to the valve frame 340, the leaflet body 396 is located within the lumen of the valve frame 340.

[0076] Referring to FIG. 11, the leaflet 390 can be positioned such that the portion of the leaflet body 396 nearest the projections 392 is pulled over the outer curved support structure 360 and the leaflet projections 392 are curved over the inner curved support structure 358. Each leaflet projection 392 can be attached by sutures 394 to itself. This anchors the leaflet projections 392 to the inner curved support structure 358 and permits the leaflet body 396 to be secured and maintain its shape within the lumen of the valve frame 340. This configuration can prevent the sutures 394 from being exposed to blood passing through the valve and can provide free motion of the leaflet body without any contact to prosthetic materials thereby preventing damage to the leaflet.

[0077] In the embodiment shown in FIG. 14, the two wires of the outer curved support structure 360 are placed very close to each other. Similar to the embodiment shown in FIG. 11, the leaflet 390 is positioned such that the portion of the leaflet body 396 nearest the projections 392 is pulled over the outermost wire of the outer curved support structure 360. Each of the leaflet projections 392 then passes through the space between the two wires of the outer curved support structure 360. Because the space between these two wires is designed to barely allow passage of the cover material 396, displacement of the leaflet between the docking station and the valve frame is minimized, in addition to the other advantages described in accordance with the embodiment shown in FIG. 11. Each of the leaflet projections 392 then wraps over the inner curved support structure 358 and is attached by sutures 394 to itself as in the other embodiment.

[0078] FIG. 15 depicts a similar valve frame but one in which the inner 358 and outer 360 curved support structures are attached to the same location 404 on vertices of wire 352 of the cylindrical body 352. Additionally, a plurality of standoffs 350 hold one or more exterior serpentine rings 353 at a distance away from the outer curved support structure 360 to provide extra support to the valve frame 340. At several locations on the exterior serpentine ring(s) 353 are located platinum markers 400. In some embodiments (shown) platinum wire is wrapped about the exterior serpentine ring(s) 353 in several locations. These locations then serve as radiopaque markers 400 to help position the valve frame 340 within the docking station 330. In other embodiments, the platinum markers are also positioned on the opposite end of the valve frame so that both ends of the valve frame 340 can be seen clearly under fluoroscopy as the valve frame 340 is positioned within the docking station 330. Each standoff 350 can be sufficiently long so that when the valve frame 340 is compressed to fit within a catheter, the leaflet 396 which is turned over the outer support structure 360 does not contact the exterior serpentine ring 353 thereby potentially causing damage to the leaflet 390. Similar platinum markers can be positioned on one or both ends of any of the valve frames described hereinabove, including the valve frames shown in FIGS. 8 and 12.

[0079] With reference to FIGS. 16A-16D, general method steps associated with the implantation of a transcatheter heart valve prosthesis according to the present teachings are described. By way of example, the method steps relate to implantation of the prosthesis in the aortic position; however, implantation of the prosthesis in other anatomical positions, for example, at the pulmonary valve position, is within the scope of the present teachings.

[0080] Referring to FIG. 16A, an introducing catheter 61 is delivered via a femoral vessel by means of a guidewire 62 to the ascending aorta 68 at a position distal to the native aortic valve (away from the left ventricle). The introducing catheter 61 has an inner wall 69 that defines a lumen 64 through which the guidewire 62 is passed. The introducing catheter 61 has an opening 66 out of which the guidewire 62 is extended.

[0081] With reference also to FIG. 16B, a docking station/balloon combination 71 is inserted into the introducing catheter 61 and is guided to the ascending aorta 68 using the guidewire 62. The combination 71 is then deployed from the confines of the introducing catheter 61 and at least a portion of the docking station is positioned proximal to the native aortic valve 63. The docking station/balloon combination 71 can include a balloon 73 located within a lumen 75 of the docking station 77. In some embodiments, the docking station/balloon combination 71 can be positioned within the introducing catheter 61 prior to inserting the introducing catheter 61 into the anatomical lumen 65. In other embodiments, the docking station/balloon combination 71 can be inserted into the introducing catheter 61 after the opening 66 of the introducing catheter 61 has been located at the ascending aorta. As shown in FIG. 16B, the docking station/balloon combination is ready to be deployed in the same luminal space as the native aortic valve. The balloon of the deployed docking station/balloon combination is then inflated, thereby expanding the docking station to a predetermined configuration and size. The balloon is quickly deflated and withdrawn.

[0082] With reference to FIG. 16C, the deployed docking station 77 pushes the native aortic valve 63 against the wall of the aorta. As previously mentioned, such coverage and immobilization of the native heart valve typically will result in free

regurgitation; however, due to the presence of the diaphragm 78 attached to the docking station, a controlled mechanism of blood flow is provided, thereby allowing the patient's heart to stabilize prior to the introduction of the more permanent replacement heart valve.

[0083] At this point, the medical practitioner, using fluoroscopy, can determine the diameter of the deployed docking station more precisely and select a valve frame of an optimal size. Once an appropriate valve frame is selected, it is compressed and inserted into the introducing catheter and the valve frame is guided to the catheter orifice and deployed into the lumen of the expanded docking station. In some embodiments, the valve frame can be deployed in or near the position at which the diaphragm is attached to the docking station.

[0084] Referring to FIG. 16D, the valve frame 91 is deployed about the position at which the diaphragm 78 is attached within the lumen of the docking station 77. For example, the proximal portion (i.e., the portion having the valve members) of the valve frame can be positioned below where the diaphragm is attached to the docking station, while the distal portion of the valve frame can be positioned above where the diaphragm is attached. The diaphragm is pushed against the inner wall of the docking station and helps to seal any space that may exist between the docking station 77 and the valve frame 91. An additional benefit of the heart valve prosthesis of the present teachings therefore includes the provision of a sealing mechanism between the docking station and the valve frame, hence preventing any paravalvar leakage despite the fact that the valve frame 91 is adapted to expand and assume substantially the same size and shape as the lumen 75 of the expanded docking station 77 upon deployment. The introducing catheter can now be removed from the patient's body.

[0085] To further illustrate, the prosthesis of the present teachings can be implanted in the mitral position, for example, by generally following the steps described above. In particular, an introducing catheter and the prosthesis can be delivered through a femoral venous sheath, and the prosthesis can then be positioned in the left atrium and ventricle by making a hole in the atrial septum.

[0086] FIG. 17A is a side cross-section view of a deployed docking station 77 with an attached diaphragm 78 within its lumen. A deployed replacement heart valve 91 (shown as a simplified block), interchangeably referred hereinbelow as a permanent valve, is positioned just above the attachment point of the diaphragm. As shown, the leaflets of the diaphragm are pushed against the inner wall of the docking station, similar to the way the deployed docking station pushes the cusps of the aortic valve against the wall of the aorta in FIG. 16C.

[0087] FIG. 17B shows a cross-sectional view of the heart valve prosthesis of FIG. 17A along the line C-C'. The permanent valve 91 can include a plurality of leaflets 79 and one or more struts 90 that are similar to the standoffs 350 of valve frame 340 (FIGS. 7-9). As shown, the diaphragm is compressed between the docking station 77 and the permanent valve 91. FIG. 17C is an expanded view of the circled portion of FIG. 17A, which shows the potential space 92 between the docking station 77 and the permament valve 91 more clearly.

[0088] FIG. 18A is a side cross-sectional view of another embodiment of a deployed docking station 77 with an attached diaphragm 78 within its lumen. A deployed replacement heart valve 91 (shown without detail for simplification) is positioned within the narrower intermediate portion of the docking station to allow stable anchoring. Again, the leaflets of the diaphragm are pushed against the inner wall of the docking station and can be compressed between the potential space between the docking station and the replacement heart valve to help prevent or reduce paravalvar leakage (FIG. 18B).

[0089] FIGS. 19A-C show how the diaphragm can be compressed by the deployed permanent valve, thereby being rendered non-functional and non-obstructive. In some embodiments and referring to FIG. 19A, the diaphragm 78 can be compressed by the struts 90 or standoffs of the permanent valve 91. In other embodiments and referring to FIGS. 19B and 19C, the diaphragm 78 can be compressed by one or more cylindrical portions of the permanent valve 90, for example, the substantially cylindrical body portion 341 and the exterior serpentine wire ring 353 of the valve frame 340 (FIG. 7). As shown in FIGS. 19A-C, potential space 92 can be found between the leaflets of the permanent valve, between the

docking station and the permanent valve, and between the docking station and the native valve (not shown). The diaphragm pressed against the inner wall of the docking station by the deployed permanent valve can serve a secondary function of preventing paravalvar leakage due to such potential space, particularly when the diaphragm is composed of a bio-absorbent material or a material that is otherwise impermeable to blood as described in certain embodiments above, for example, by expanding to fill up the space.

[0090] Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the essential characteristics of the present teachings. Accordingly, the scope of the invention is to be defined not by the preceding illustrative description but instead by the following claims, and all changes that come within the meaning and range of equivalency of the claims are intended to be embraced therein.

[0091] What is claimed is:

CLAIMS

1. A heart valve prosthesis comprising:

a docking station comprising a wire frame defining a lumen,

a diaphragm positioned within the lumen and attached to the wire frame of the docking station, the diaphragm being adapted to have an open position and a close position, and

a replacement heart valve comprising a valve frame for positioning within the lumen of the docking station.

2. The heart valve prosthesis of claim 1, wherein the docking station has an expanded position and a compressed position.

3. The heart valve prosthesis of claim 1 or 2, wherein the docking station is self-expandable.

4. The heart valve prosthesis of claim 1 or 2, wherein the docking station is balloon-expandable.

5. The heart valve prosthesis of claims 1-4, wherein the wire frame of the docking station comprises one or more openings.

6. The heart valve prosthesis of claims 1-5 comprising a radiopaque marker on the wire frame of the docking station.

7. The heart valve prosthesis of claims 1-6, wherein the diaphragm comprises a biocompatible membrane.

8. The heart valve prosthesis of claims 1-7, wherein the diaphragm comprises one or more slits.

9. The heart valve prosthesis of claims 1-7, wherein the diaphragm comprises a plurality of leaflets.

10. The heart valve prosthesis of claim 9, wherein the leaflets are supported by one or more wires.

11. The heart valve prosthesis of claims 1-10, wherein the diaphragm comprises one or more perforations.

12. The heart valve prosthesis of claims 1-11, wherein the diaphragm is attached to the wire frame of the docking station by sutures.

13. The heart valve prosthesis of claims 1-11, wherein the diaphragm is attached to the wire frame of the docking station by adhesives.

14. The heart valve prosthesis of claims 1-13, wherein the wire frame of the docking station comprises a cylindrical portion and a bulbous portion, the diaphragm being attached to the bulbous portion of the wire frame.

15. The heart valve prosthesis of claims 1-14, wherein the valve frame of the replacement heart valve comprises a substantially cylindrical body defining a lumen and a plurality of valve members attached to the substantially cylindrical body, each of the valve members comprising one or more curved wires and a leaflet.

16. The heart valve prosthesis of claim 15, wherein each of the valve members of the replacement heart valve comprises an inner curved wire support structure and an outer curved wire support structure.

17. The heart valve prosthesis of claim 16, wherein the leaflet of the valve member of the replacement heart valve comprises a leaflet body and one or more leaflet projections.

18. The heart valve prosthesis of claim 17, wherein the one or more leaflet projections are attached to a respective inner curved support structure and the leaflet body extends over a respective outer curved support structure, so as to position the leaflet body within the lumen of the valve frame of the replacement heart valve.

19. A method of delivering a heart valve prosthesis to an anatomical site, the method comprising the steps of:

introducing a heart valve prosthesis into the heart through a catheter, the heart valve prosthesis comprising a docking station comprising a wire frame defining a lumen and a diaphragm comprising a plurality of leaflets and adapted to have an open position and a close position;

deploying the docking station;

introducing a replacement heart valve into the lumen of the docking station through a catheter, the replacement heart valve comprising a valve frame and a plurality of valve members; and

deploying the replacement heart valve within the lumen of the docking station so that the leaflets of the diaphragm are pressed between the wire frame of the docking station and the valve members of the replacement heart valve.

20. The method of claim 19 further comprising determining a diameter of the deployed docking station using fluoroscopy.

21. The method of claim 20, wherein the replacement heart valve has a diameter that approximates the diameter of the deployed docking station.

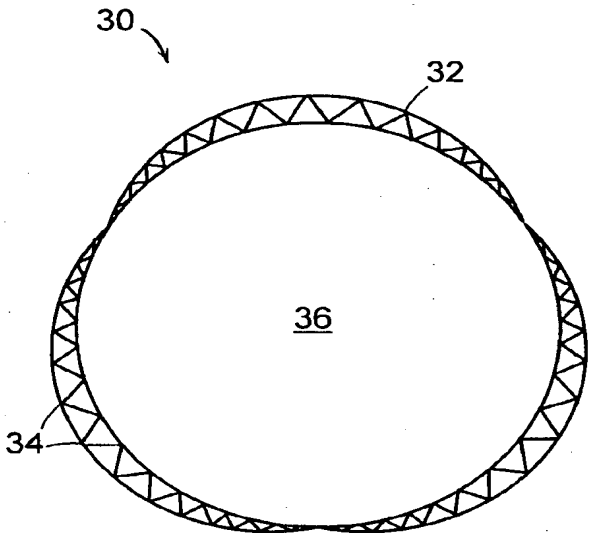


FIG. 1A

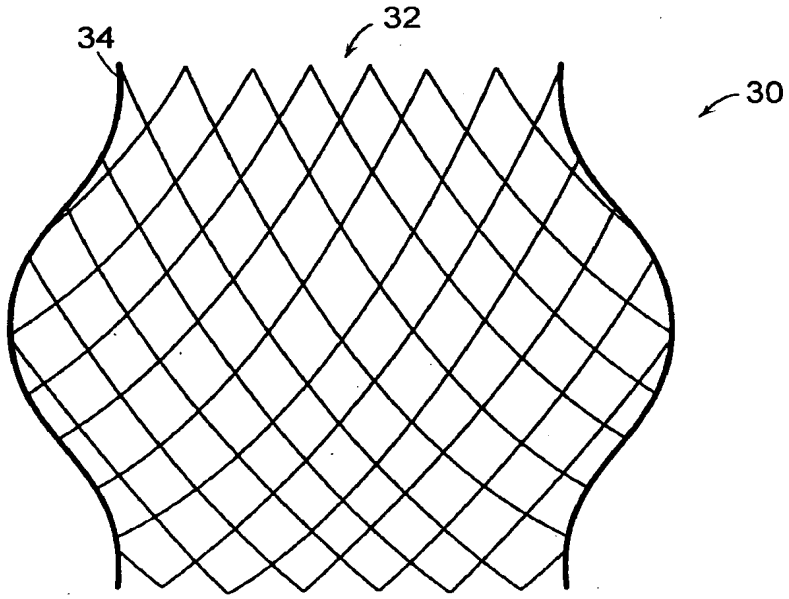


FIG. 1B

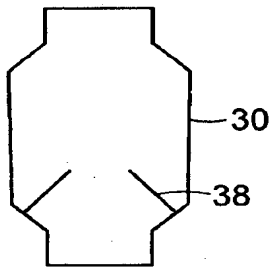


FIG. 2A

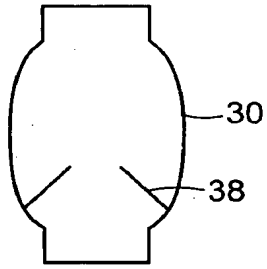


FIG. 2B

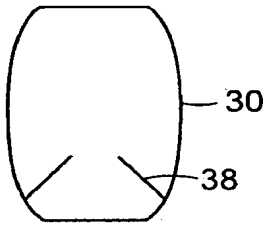


FIG. 2C

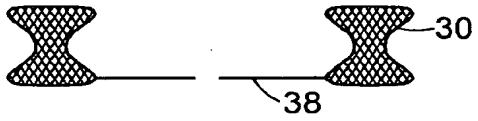


FIG. 2D

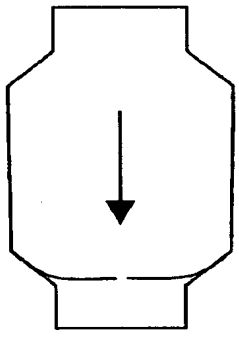


FIG. 3A

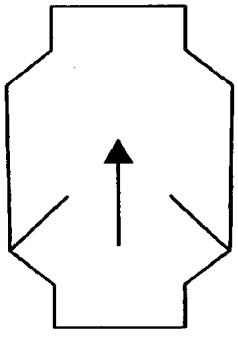


FIG. 3B

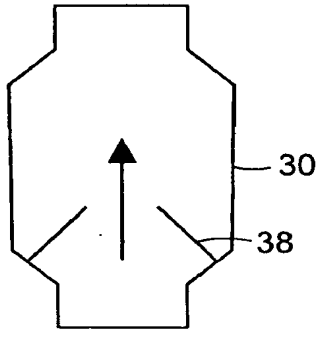


FIG. 3C

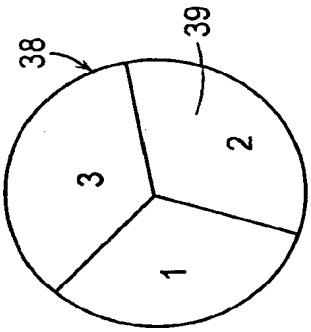


FIG. 4A

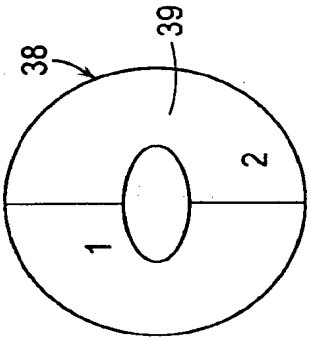


FIG. 4B

FIG. 4C

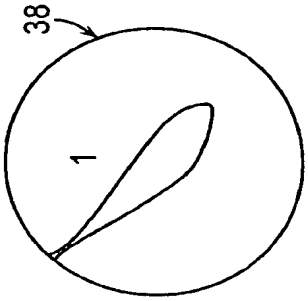


FIG. 4D

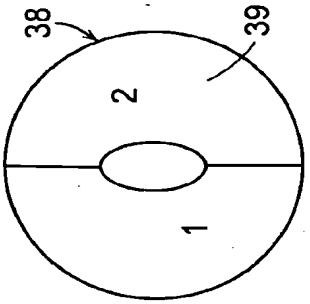


FIG. 4E

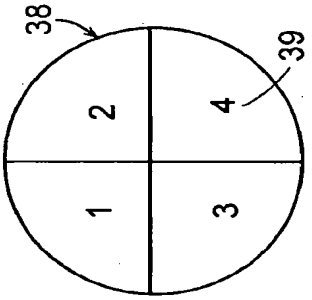


FIG. 4F

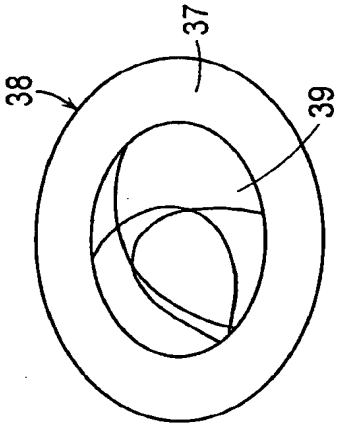


FIG. 4I

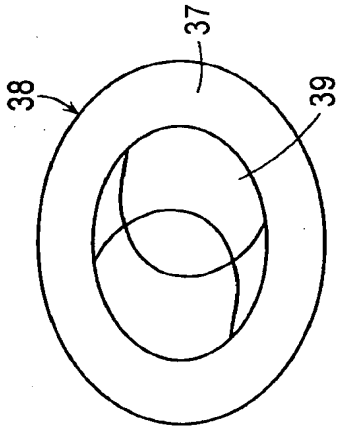


FIG. 4H

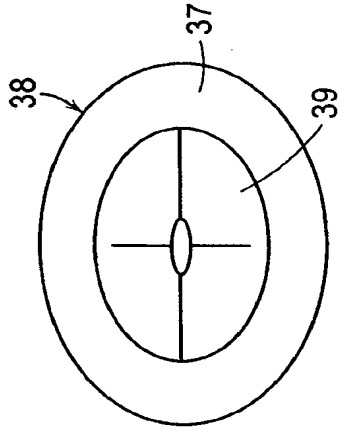


FIG. 4G

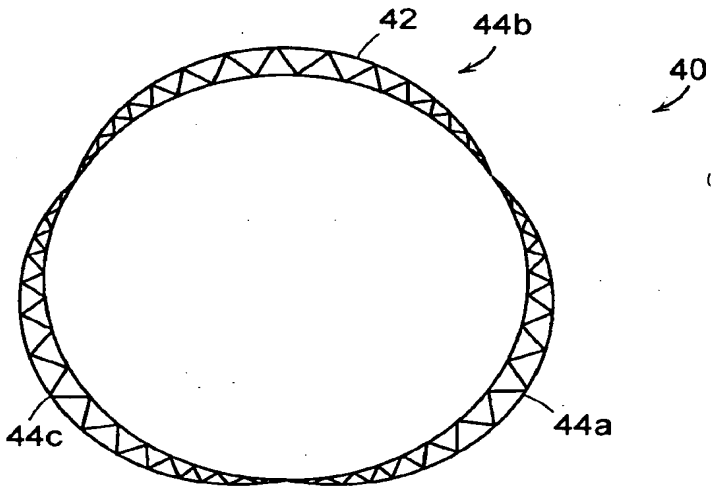


FIG. 5A

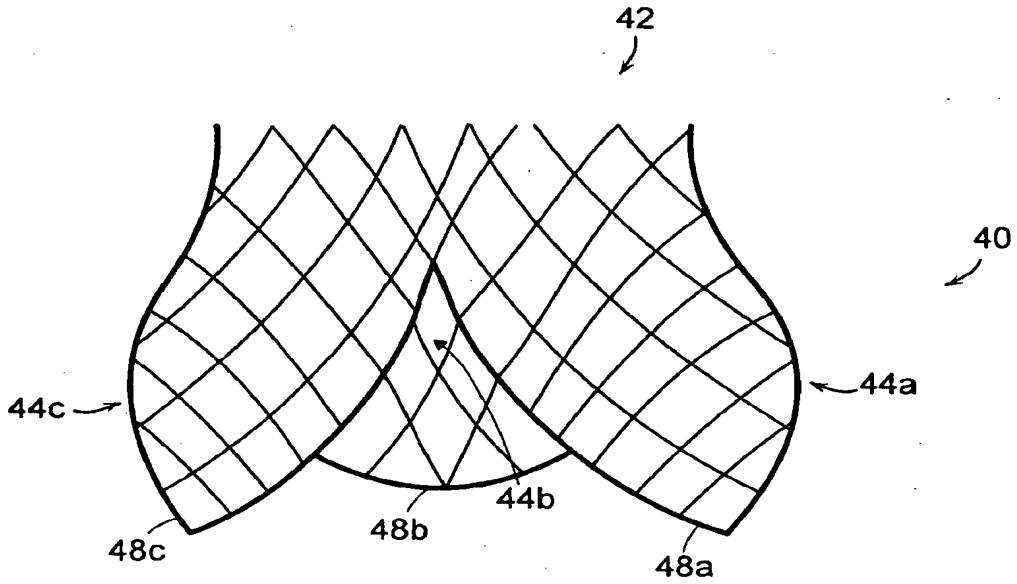


FIG. 5B

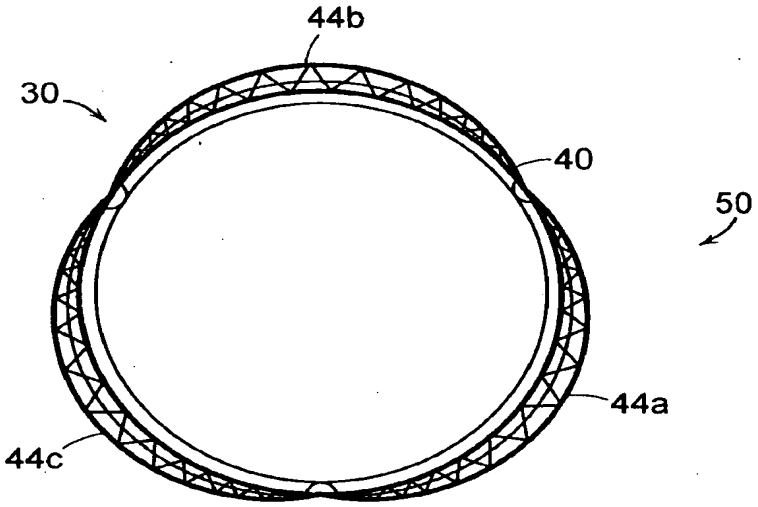


FIG. 6A

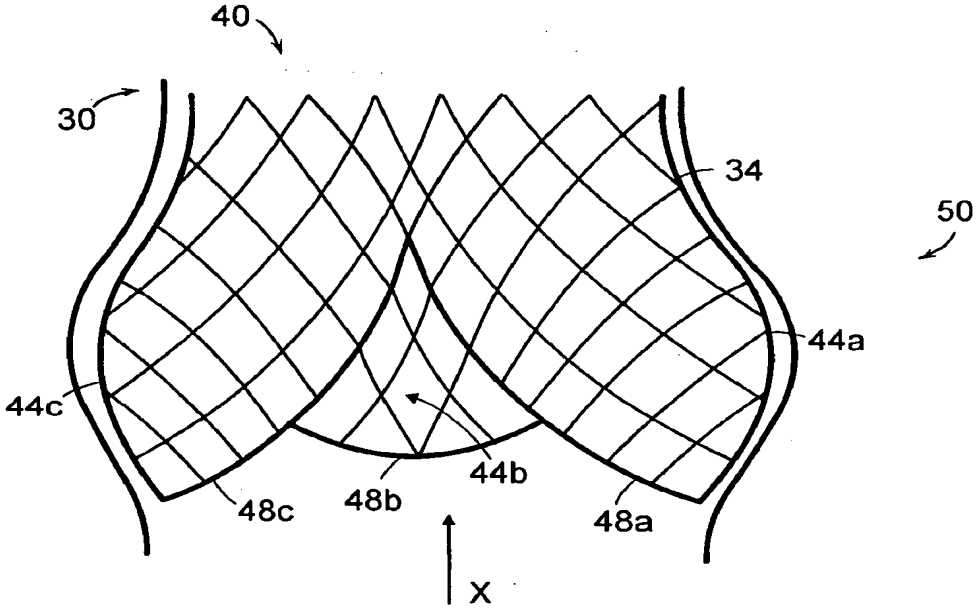


FIG. 6B

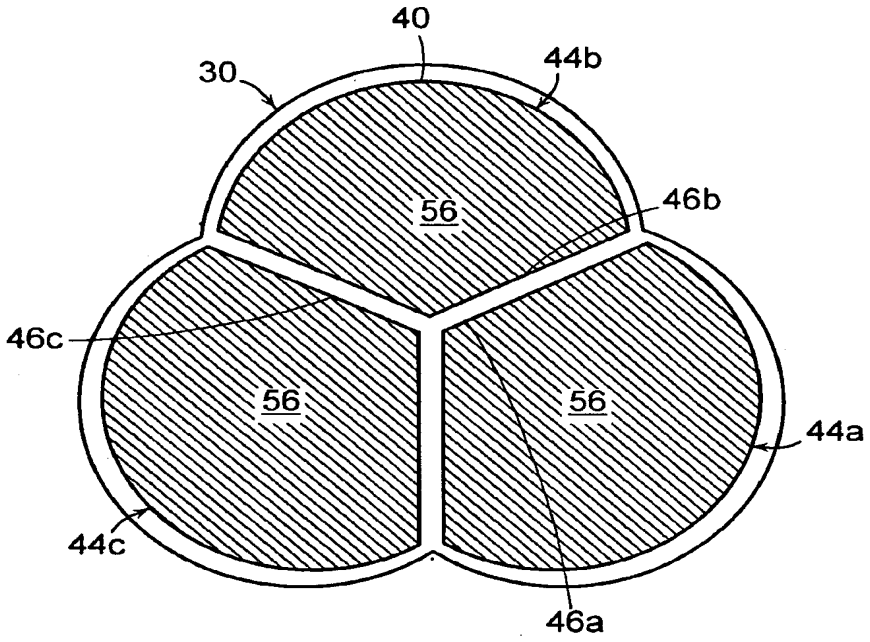


FIG. 6C

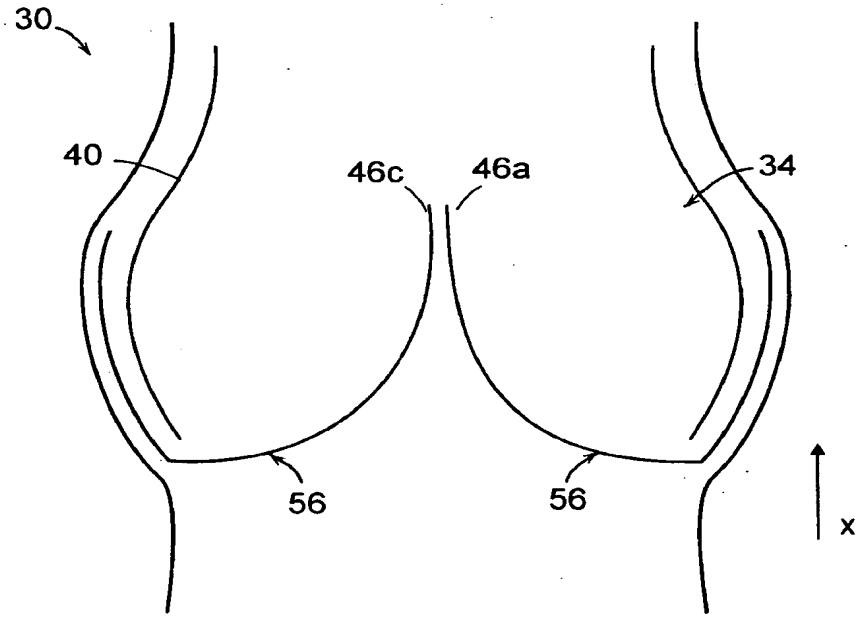


FIG. 6D

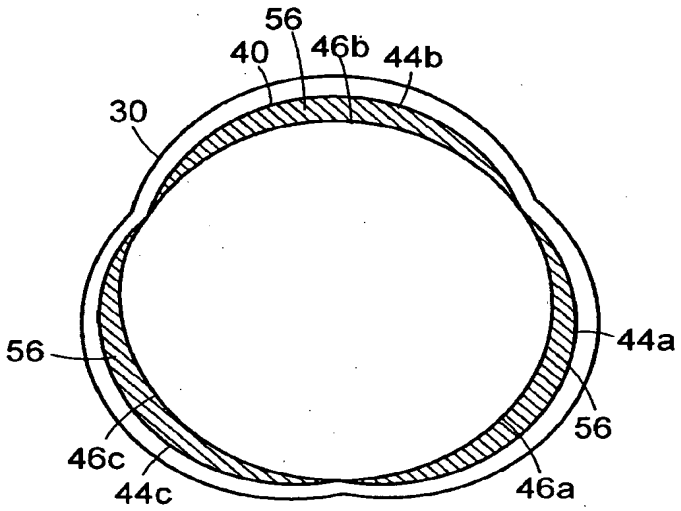


FIG. 6E

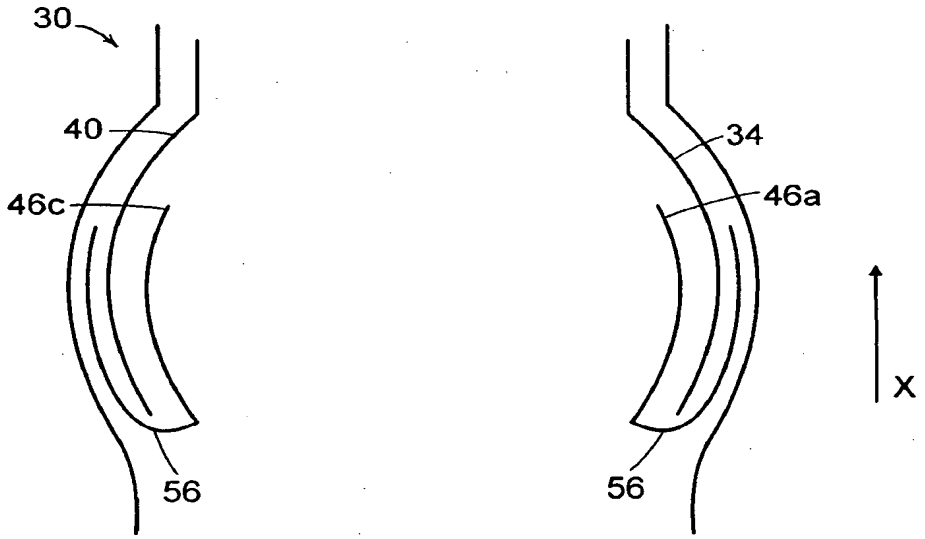


FIG. 6F

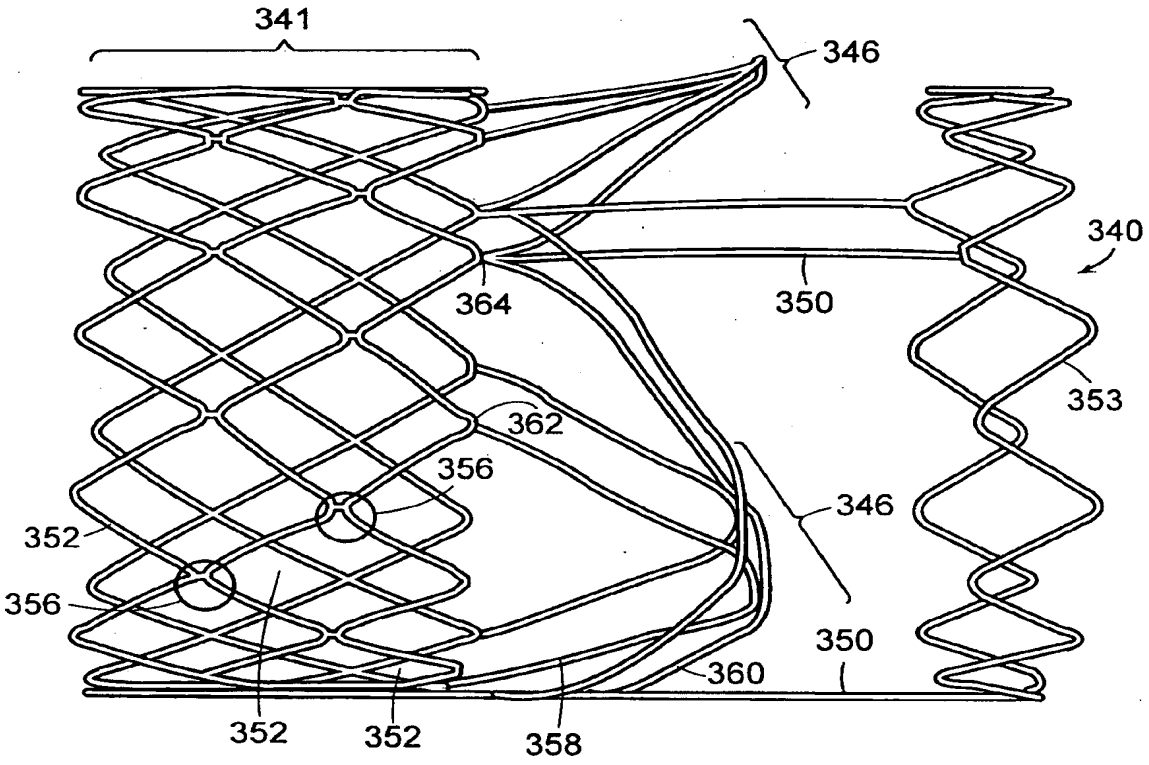


FIG. 7

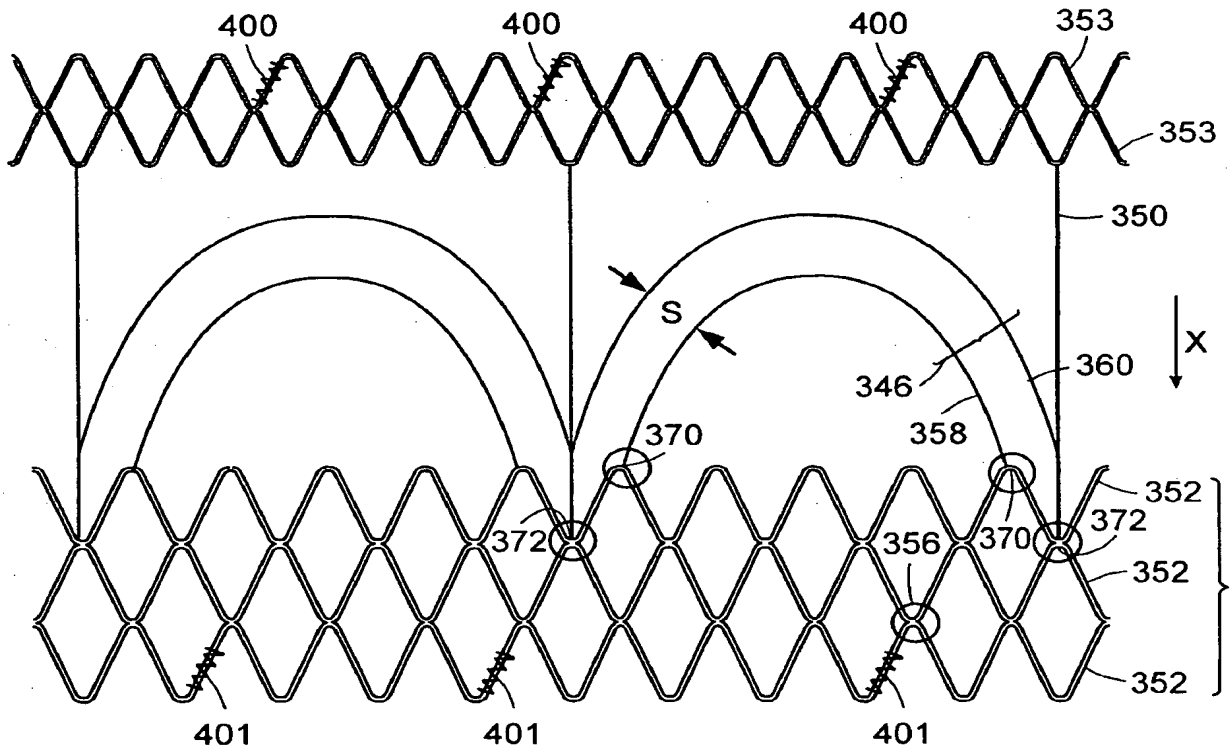

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FIG. 8

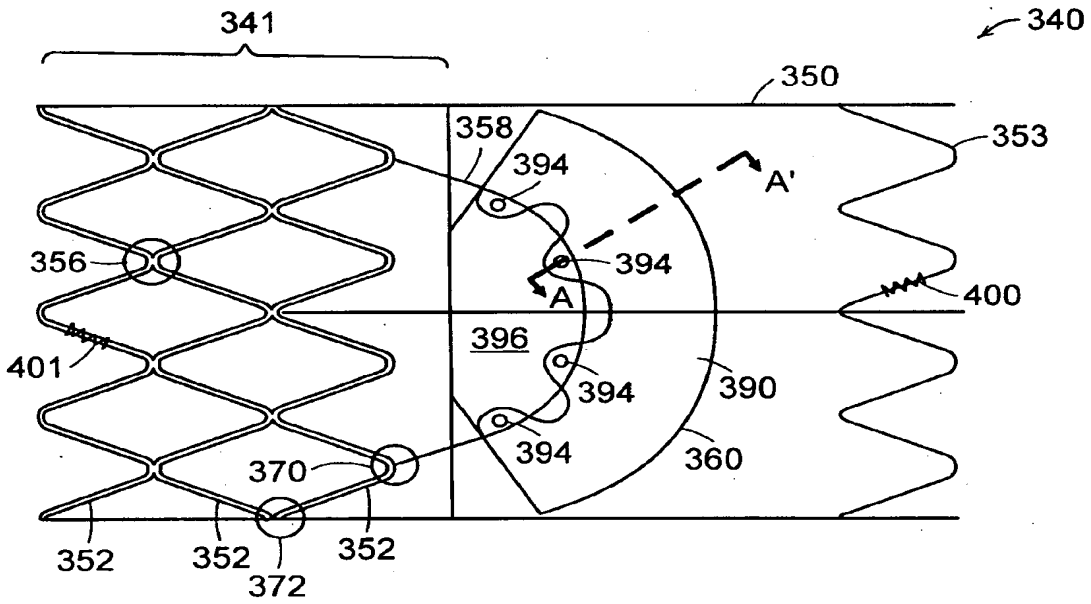

FIG. 9

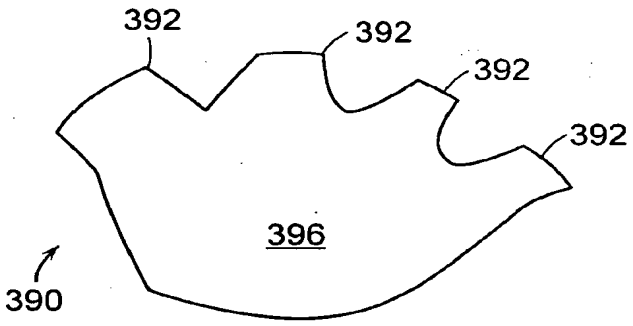

FIG. 10

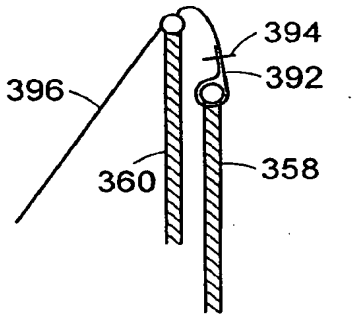

FIG. 11

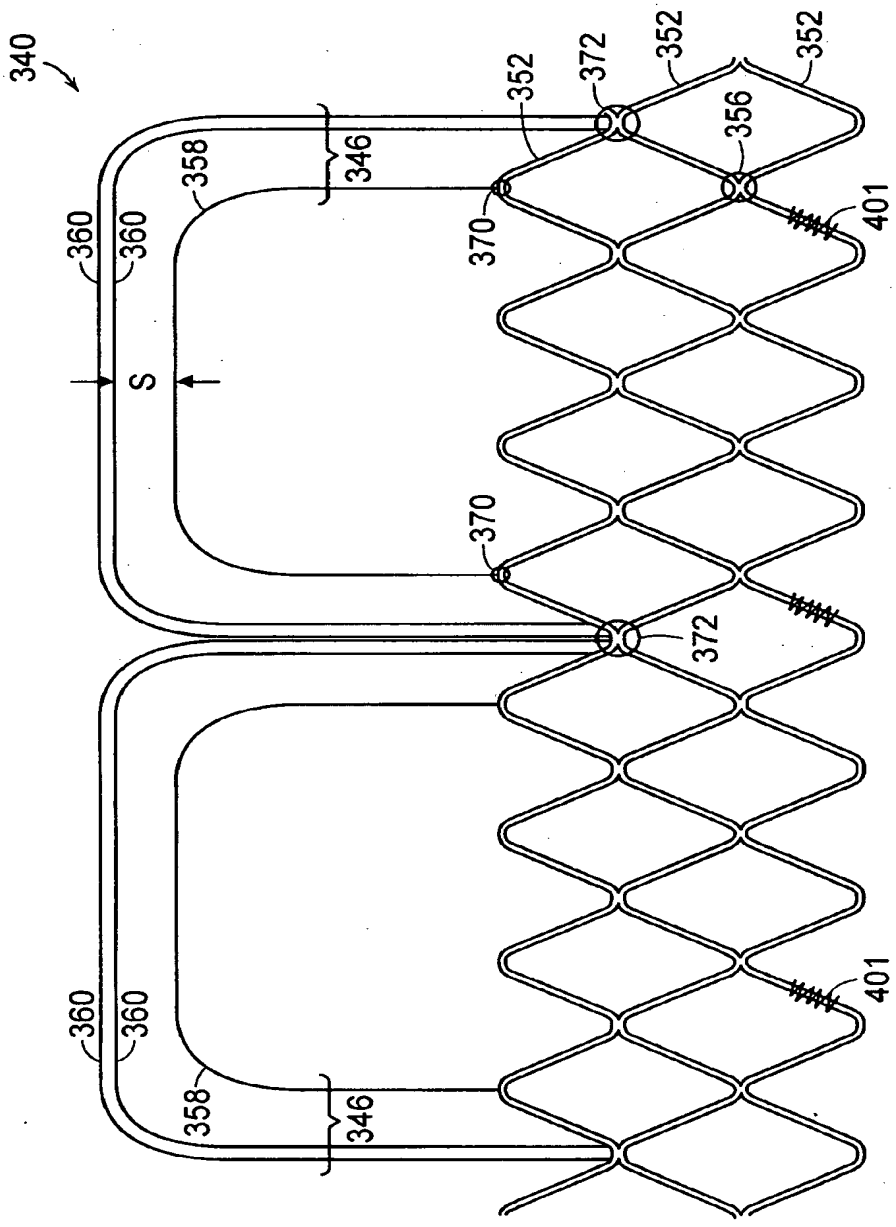
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FIG. 12

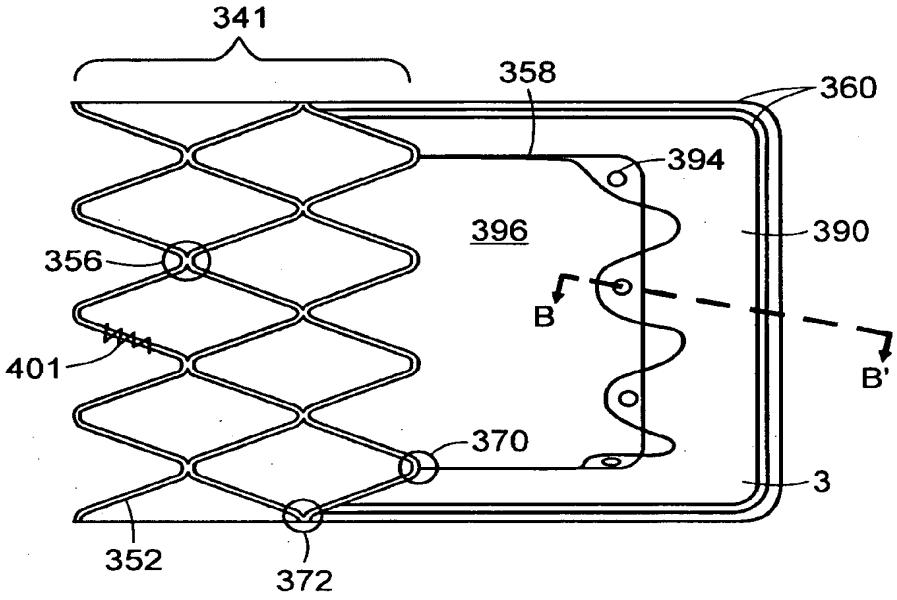
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FIG. 13

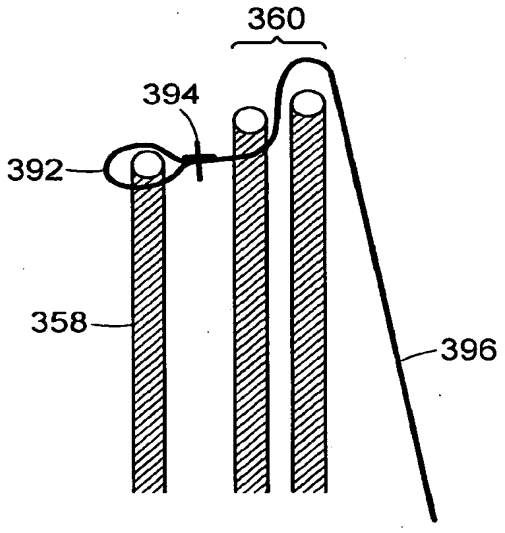
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FIG. 14

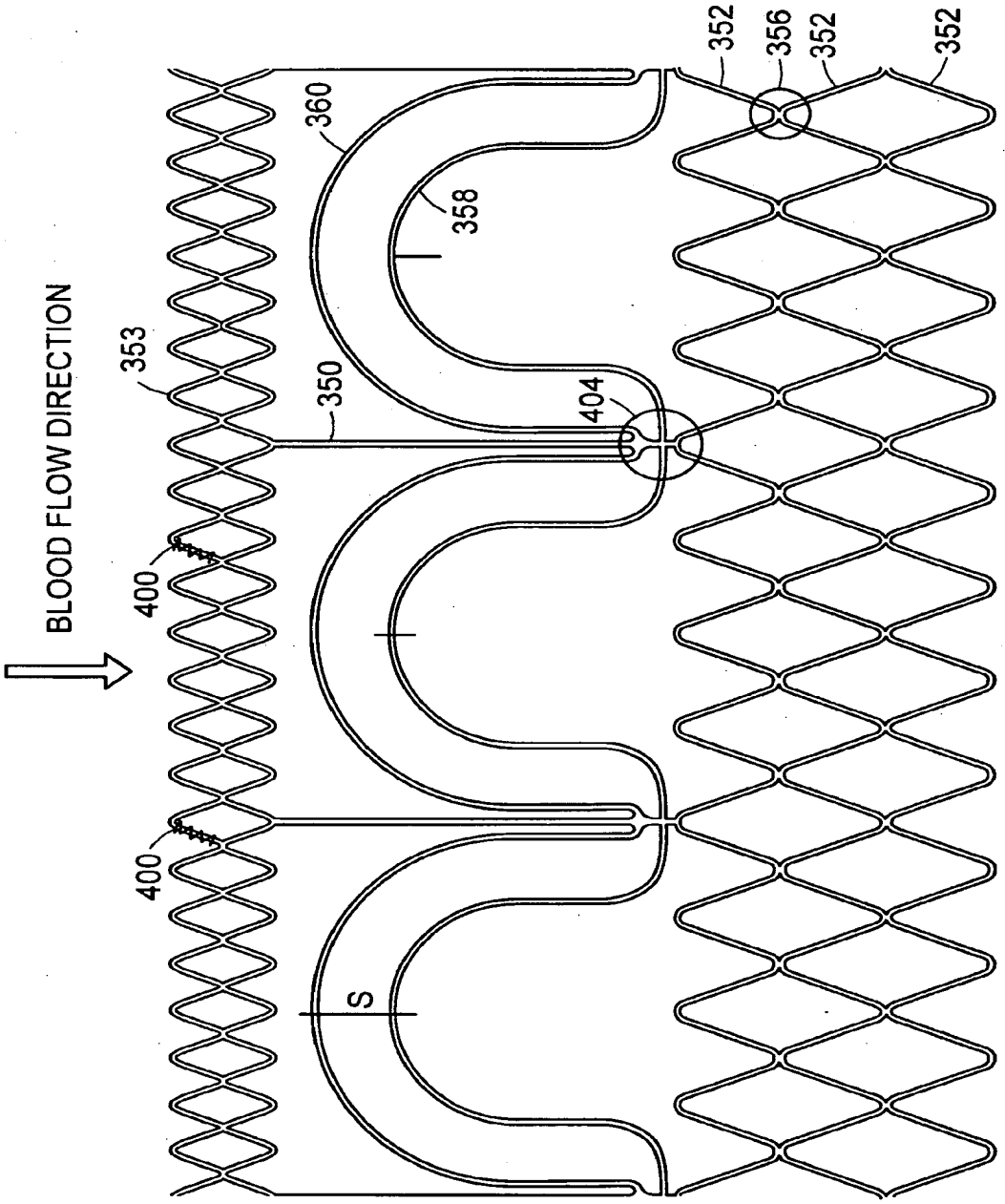
BLOOD FLOW DIRECTION
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FIG. 15

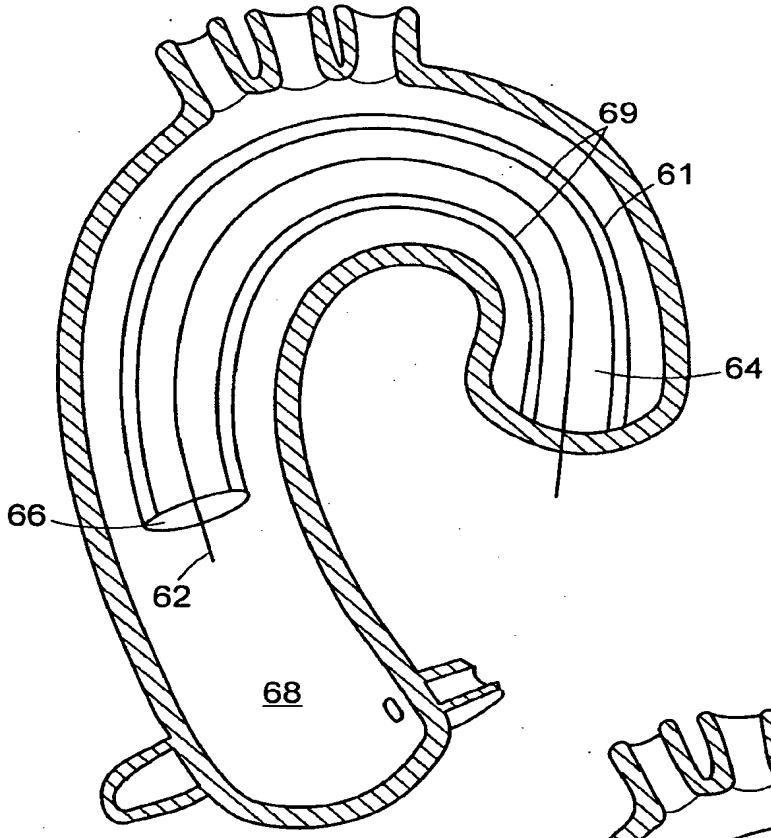


FIG. 16A

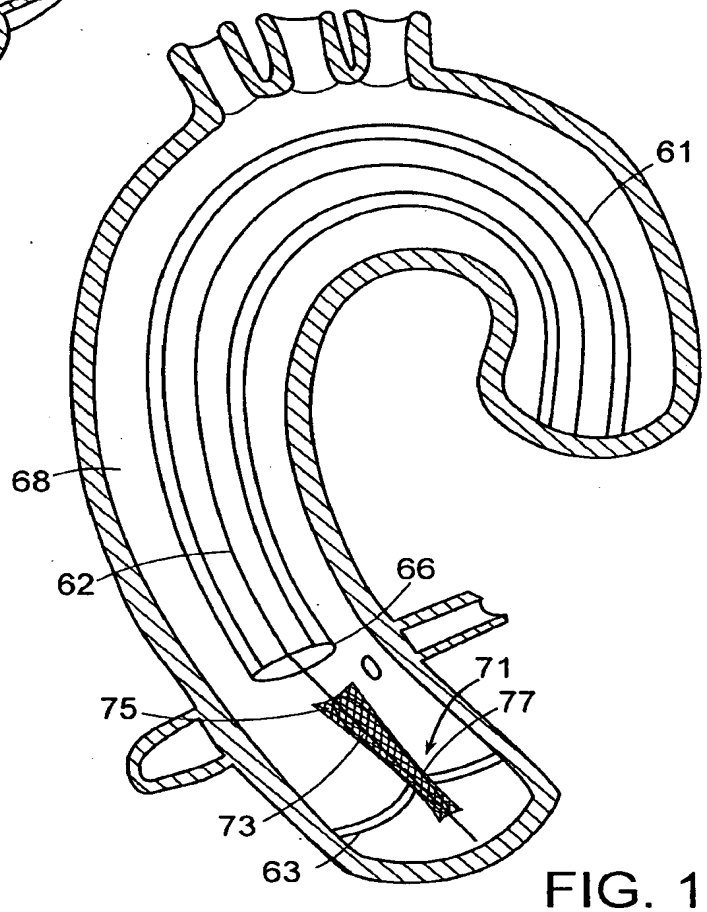


FIG. 16B

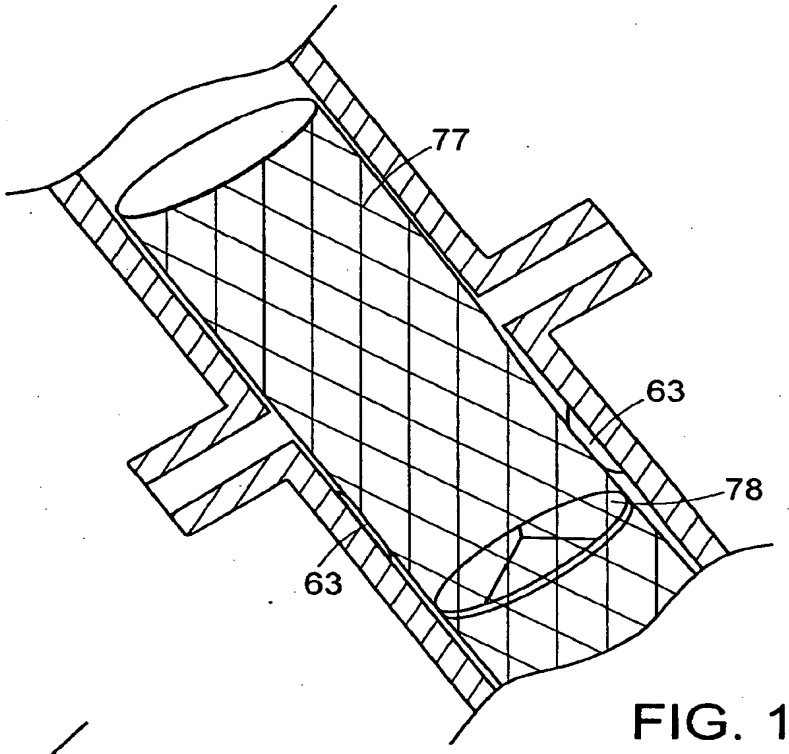


FIG. 16C

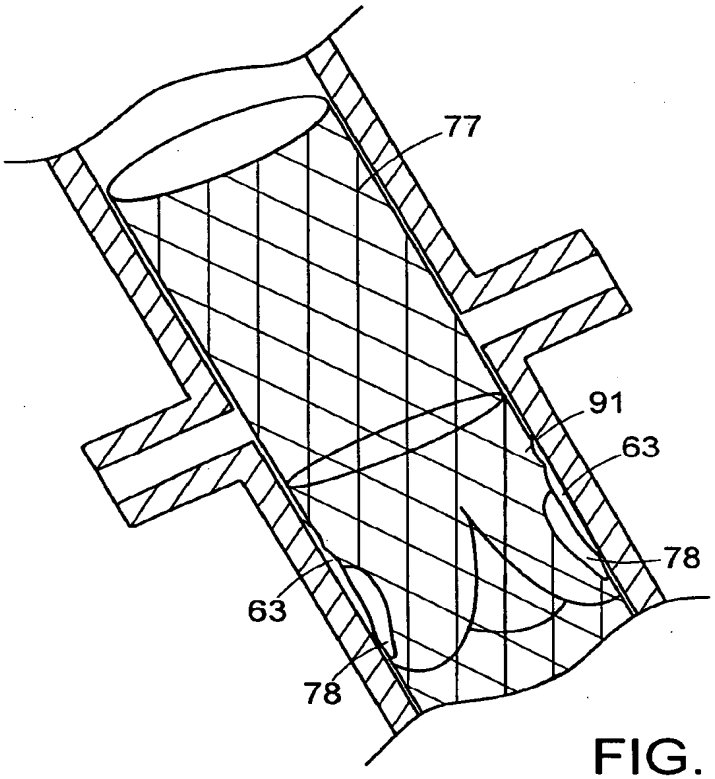


FIG. 16D

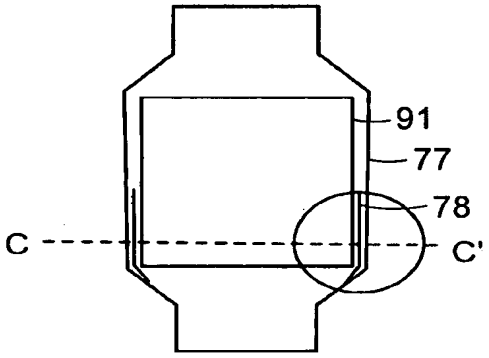


FIG. 17A

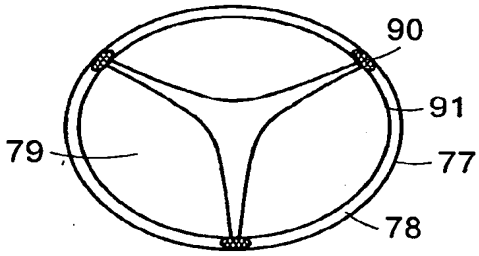


FIG. 17B

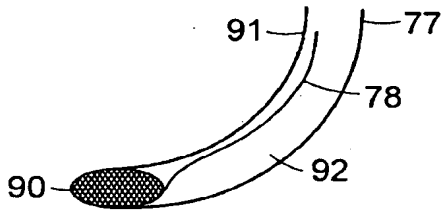


FIG. 17C

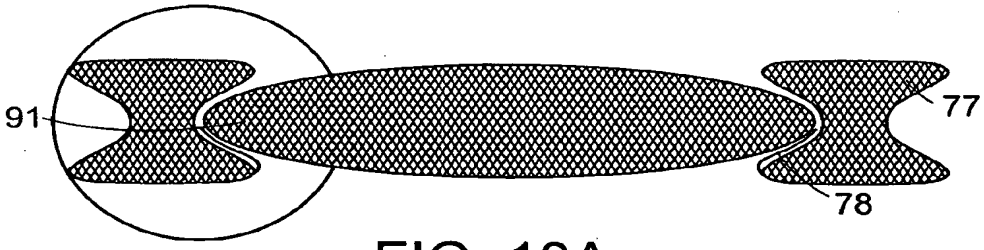


FIG. 18A

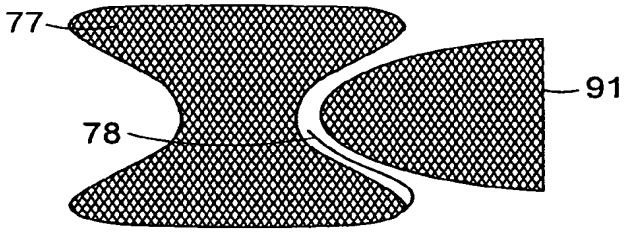


FIG. 18B

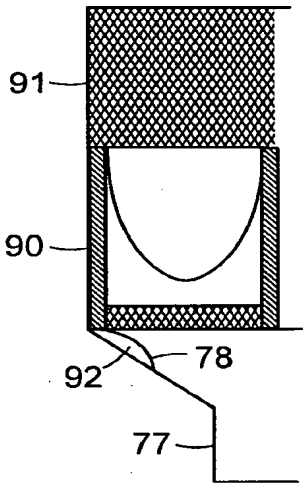


FIG. 19A

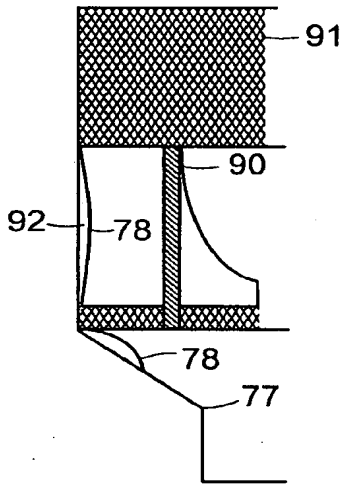


FIG. 19B

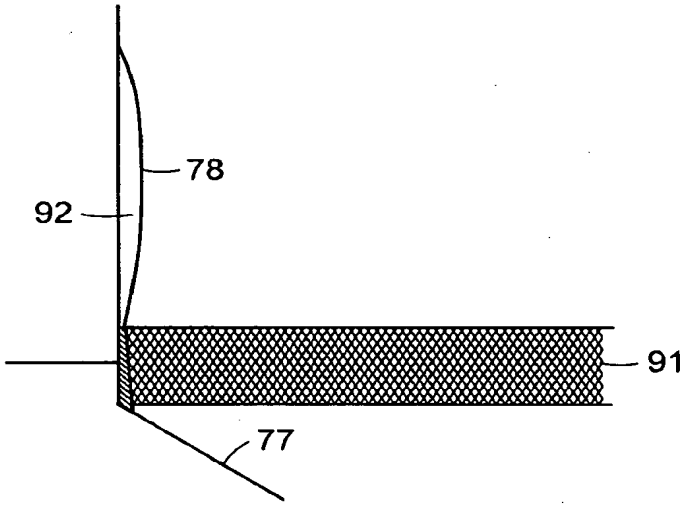


FIG. 19C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/010768

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/049262 A1 (OBERMILLER JOSEPH F [US] ET AL) 11 March 2004 (2004-03-11) paragraphs [0029] - [0032], [0040], [0043]; figures 10-19	1-18
A	WO 00/44313 A1 (VIACOR INC [US]; LAMBRECHT GREGORY H [US]; LIDDICOAT JOHN [US]; MOORE) 3 August 2000 (2000-08-03) the whole document	1-18
A	US 2005/043790 A1 (SEGUIN JACQUES [GB]) 24 February 2005 (2005-02-24) the whole document	1-18

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 October 2007	17/10/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	PRECHTEL, A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/010768

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/010768

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004049262 A1	11-03-2004	US 2005096736 A1	05-05-2005
WO 0044313 A1	03-08-2000	AU 764886 B2	04-09-2003
		AU 2633200 A	18-08-2000
		CA 2361670 A1	03-08-2000
		CN 1347297 A	01-05-2002
		EP 1154738 A1	21-11-2001
US 2005043790 A1	24-02-2005	CA 2450935 A1	16-01-2003
		EP 1401359 A2	31-03-2004
		FR 2826863 A1	10-01-2003
		WO 03003949 A2	16-01-2003
		JP 2005505320 T	24-02-2005

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2007 (27.12.2007)

PCT

(10) International Publication Number
WO 2007/149933 A2

(51) International Patent Classification:
A61F 2/24 (2006.01)

(21) International Application Number:
PCT/US2007/071689

(22) International Filing Date: 20 June 2007 (20.06.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/805,420 21 June 2006 (21.06.2006) US

(71) Applicant *(for all designated States except US)*: **AORTX, INC.** [US/US]; 2686-A Middlefield Road, Redwood City, California 94062 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **FORSTER, David C.** [US/US]; 13100 Byrd Lane, Los Altos, California 94025 (US). **BECKEY, Brian** [US/US]; 1330 Crazy Petes Road, Woodside, California 94062 (US). **WALSH, Brandon** [US/US]; 1392 W. 2175 South, Syracuse, Utah 94304-1050 (US). **HENEVELD, Scott** [US/US]; 12400 Arrows Way, Whitmore, California 96096 (US).

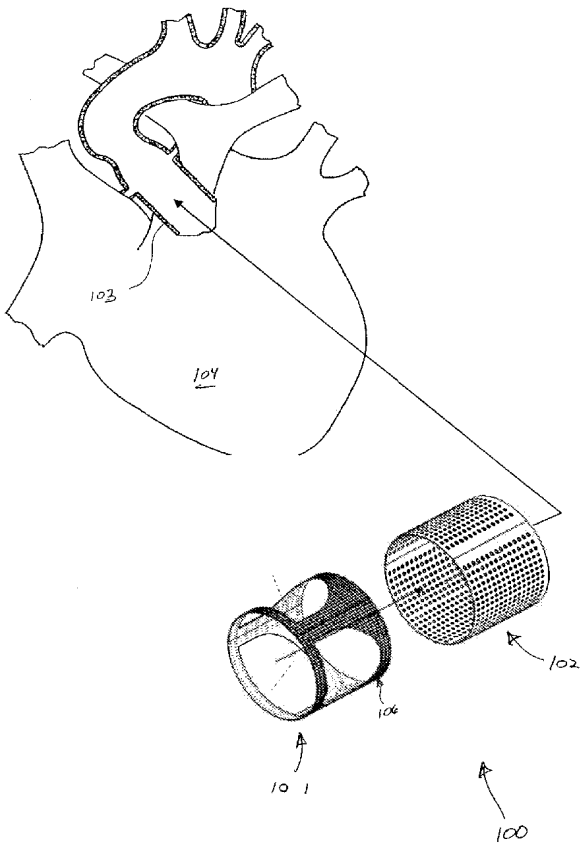
(74) Agents: **ORRICK HERRINGTON & SUTCLIFFE LLP** et al.; 4 Park Plaza, Suite 1600, Irvine, California 92614-2558 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: PROSTHETIC VALVE IMPLANTATION SYSTEMS



(57) Abstract: Prosthetic valves implantation methods and systems, especially as related to fitting a prosthetic valve at the site of a native stenotic or incompetent valve are described. The subject devices, systems and associated dock deployment and implant docking techniques may be employed in percutaneous valve replacement procedures.

WO 2007/149933 A2

European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PROSTHETIC VALVE IMPLANTATION SYSTEMS

BACKGROUND OF THE INVENTION

[0001] Diseases and other disorders of the heart valves affect the proper flow of blood from the heart. Two categories of heart valve disease are stenosis and incompetence. Stenosis refers to a failure of the valve to open fully, due to stiffened valve tissue. Incompetence refers to valves that cause inefficient blood circulation by permitting backflow of blood in the heart.

[0002] Medication may be used to treat some heart valve disorders, but many cases require replacement of the native valve with a prosthetic heart valve. Prosthetic heart valves can be used to replace any of the native heart valves (aortic, mitral, tricuspid or pulmonary), although repair or replacement of the aortic or mitral valves is most common because they reside in the left side of the heart where pressures are the greatest.

[0003] Conventional heart valve replacement surgery involves accessing the heart in the patent's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart, allowing access to the thoracic cavity and heart within. The patient is then placed on cardiopulmonary bypass support which involves stopping the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period.

[0004] Percutaneous implantation of a prosthetic valve is a preferred procedure because the operation is performed under local anesthesia, may not require cardiopulmonary bypass, and is less traumatic. Various types of prosthetics are adapted for such use. One class employs a stent like outer body and internal valve leaflets attached thereto to provide one way blood flow. These stent structures are radially contracted for delivery to the intended site, and then expanded/deployed to achieve a tubular structure in the annulus. Another more advantageous class is offered by the assignee hereof. US Patent Publication No. 2005/0203614 (hereinafter "the '614 application," which application is incorporated by reference herein in its entirety) describes a system in which various panels define the implant body carrying valve leaflets. These prosthetic valve structures are delivered in a contracted state and then unfolded and/or unrolled into an expanded state at the treatment location. An example of such a valve is depicted in FIG. 1A. As shown, valve prosthesis 101 is adapted to carry a valve 107 having multiple leaflets 108. The valve support structure 106 includes a plurality of panels 109 that can transition from the state shown to an inverted state as described in the '614 publication.

[0005] With either type of structure, a sufficient engagement between patient body tissue and the prosthesis body is desired to secure the position of the implant and form a peripheral seal. However, when implanting the prosthetic device at the site of/within the envelope of the native valve, the condition of the native valve can interfere with fit. Stated otherwise, irregularity in the shape of the implantation site, surface features, texture, and composition pose challenges for developing an implant of a regular size able to accommodate all such variability.

[0006] Aspects of the invention optionally address the challenges presented by prosthetic member interface with calcific and/or irregular valve leaflet and annulus geometry. In addition, other advantages of the present invention may be apparent to those with skill in the art upon review of the subject disclosure.

BRIEF SUMMARY OF THE INVENTION

[0007] This summary is provided by way of exemplary embodiments. In no way is this summary intended to provide limitation to the scope of the appended claims.

[0008] Accordingly, the systems and methods described herein include "docking" type devices for interfacing with replacement prosthetic valves. In some exemplary embodiments, these docking devices are in the form of a sleeve adapted to secure a valve body within a central lumen, and interface with native tissue around its periphery. The docking sleeves can be adapted to provide a seal between the native valve or vessel and the valve body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The figures provided herein are not necessarily drawn to scale, with some components and features being exaggerated for clarity. Each of the figures diagrammatically illustrates aspects of the invention. Variation of the invention from the embodiments pictured is contemplated.

[0010] FIG. 1A is a perspective view depicting an exemplary valve prosthesis.

[0011] FIG. 1B is an illustrative view depicting an exemplary embodiment of a docking system drawing relation to a heart.

[0012] FIGs. 2A-C are cross-sectional views depicting an exemplary embodiment of a docking system 100.

[0013] FIGs. 3A-B are axial and radial cross-sectional views, respectively, depicting additional exemplary embodiments of docking sleeve.

[0014] FIGs. 4A-B are axial cross-sectional and perspective views, respectively, depicting

another exemplary embodiment of a docking sleeve.

DETAILED DESCRIPTION OF THE INVENTION

[0015] As opposed to known systems, an aspect of the systems and methods described herein contemplates more than a simple docking ring with a limited implant-retention interface. In the systems and methods described herein, the sleeve is adapted to receive at least half, and more typically the entire valve body. Such overlap provides for valve/sleeve interface or securing approaches elaborated upon below. FIG. 1B is a illustrative view depicting a docking system 100 having a support structure 106 of a valve prosthesis 101 as described in the '614 publication and a corresponding docking sleeve 102 adapted to receive valve support structure 106. Placement of the docking sleeve 102 can occur in a location corresponding to the presence of a native valve, such as the aortic valve within the aorta 103 of the heart 104 of a patient.

[0016] Another aspect of the systems and methods described herein that distinguish them from known stent-like and simple stent-graft docking structures is that the sleeves described herein offer a space-filling function to provide each of a good interface with irregular anatomy and a central lumen having a regular shape (e.g., circular, oval or elliptical) to accommodate corresponding valve body geometry. Stated otherwise, docking sleeves are provide that adapt to or take-up space and/or compress or expand in sections to provide a superior vessel-side interface while offering an inner lumen with more regular geometry than the implantation site for valve body retention.

[0017] FIGs. 2A-C are cross-sectional views depicting an exemplary embodiment of a prosthesis 101 during various stages of deployment within aorta 103. In this embodiment, docking sleeve 102 is configured as a tissue graft with a variable thickness to conform to the underlying vessel anatomy (in this example, within aorta 103). Of course, in other embodiments, docking sleeve 102 can be composed of man-made materials and/or can be configured in a manner that does not enact full conformation with the underlying anatomy. FIG. 2A depicts graft 102 carried on an expandable member (e.g., a balloon) 110 in its unexpanded state disposed on an elongate member (e.g., a catheter shaft) 111. FIG. 2B depicts graft 102 in a deployed configuration against the walls of aorta 103 and filling sinus 112. The deployment of graft 102 is accomplished by inflation of balloon 110. FIG. 2C depicts graft 102 following the removal of balloon 110 and shaft 111 and the deployment of valve structure 106 (leaflets not shown). Here, it can be seen that structure 106 has a lesser length that graft 102, allowing greater freedom in the placement of structure 106. Also, graft 102 provides

space-filling conformance with the underlying anatomy.

[0018] Such space-filling may be provided by a compliant body or body portion (e.g., biocompatible "spongy" foam such as expanded PTFE, deflectable panels or leaf springs for a metallic material such as NiTi, a microporous polymer or metal/metal alloy, etc.), a multi-component/segment or composite body, or a body with a rigid implant-interface lumen and expandable exterior (e.g., as provided by a hydrogel, or permanently inflatable structure – via air, saline or another biocompatible fluid).

[0019] For a multi-component sleeve body, inner and outer tubular (e.g., cylindrical) sections may be provided with a spring media provided therebetween. Multiple elastomeric beams or metal spring (coil, torsion, zig-zag, etc.) elements may be employed for such purposes. Alternatively, an air-spring approach with an interposed balloon (distensible or non-distensible) may be utilized. In the latter case, no additional seal element is required between the inner and outer sleeve housings. However, in the former case, one or more baffle structures (e.g. provided by woven fabric/fiber) may be employed to seal the body from inadvertent blood flow or passage/leakage. In order to avoid inadvertently supplying a cavity prone to thrombus formation, multi-piece sleeve bodies will typically be sealed-off at both ends.

[0020] FIGs. 3A-B are axial and radial cross-sectional views, respectively, depicting additional exemplary embodiments of docking sleeve 102 having an inner sleeve 114 and an outer sleeve 115. In FIG. 3A, inner sleeve 114 (which can also be valve support structure 106) and outer sleeve 115 are in spaced relation to each other in the deployed configuration with multiple spring elements 117, which are coiled springs in this embodiment, located and exerting force between the outer surface of inner sleeve 114 and the inner surface of outer sleeve 115. Spring elements 118 serve to provide conformance to the underlying anatomy as well as to center inner sleeve 114 with respect to outer sleeve 115. Empty region 116 is configured to receive valve support structure 106 (not shown). Covering 118, which is a flexible fabric in this embodiment, is placed over the gap between sleeves 114 and 115 to seal the region therebetween from blood flow.

[0021] In FIG. 3B, docking sleeve 102 is shown in an exemplary intermediate undeployed configuration. Here, sleeves 114 and 115 are in a "tri-star" configuration similar to that described in the incorporated '614 application. Here, device 102 has three segments 123 arranged in a star-like manner. From this configuration, the profile of the device to be reduced further by rolling each segment towards the center axis 124. Sleeves 114 and 115 can be made to enter this configuration by inverting or deflecting each of panels 121 and 122, respectively,

towards the center axis 124 of the device in a manner similar to that described in the '614 application. Hinges 119 and 120 are included between panels 121 and 122, respectively, to facilitate transition between the tri-star and deployed configurations. Although spring elements 117 can also be seen, covering 118 is not shown for clarity.

[0022] The length of the sleeve may vary as alluded to above. In order to bridge irregular anatomy such as the aortic sinus, the docking sleeve may be elongated relative to the valve body.

[0023] In a procedure for implanting a docking sleeve and prosthetic valve according to the present invention, various tissue modification techniques as described in commonly assigned, "Prosthetic Valve Implant Site Preparation Techniques," provisional application serial number 60/805,333, filed on June 20, 2006 and incorporated by reference in its entirety, can be performed. However, in many instances, the current invention will allow foregoing approach without ill effect.

[0024] In one variation of the invention, a method is provided in which the docking sleeve is situated where its implantation is desired during a valvuloplasty procedure. After crossing the native valve leaflets, a balloon is expanded to simultaneously open the leaflets and deploy the docking sleeve.

[0025] In order that the interfacing valve is readily available to complete the procedure without compromising patient hemodynamics for an extended period during a beating heart procedure (given that the native valve leaflets are pinned behind the docking sleeve), the valve delivery device may also already be positioned in the aorta for immediate valve body insertion following docking sleeve or station deployment. Such a situation is facilitated by accessing the femoral artery in each leg of a patient to feed the different implant delivery systems (one from the right, and one from the left) into the aortic arch where there is sufficient room to accommodate both.

[0026] Alternatively, a temporary valve structure such as described in US Publication No. 2004/0225354 may be provided to allow advancement and delivery of the sleeve, withdrawal of its delivery catheter or guide and substitution for a valve body delivery guide for secondary implant delivery. US Publication No. 2001/0044591 discloses other approaches for percutaneous implant delivery that may alternatively be employed for delivering the docking sleeve and valve body.

[0027] As described above, the docking sleeve may be delivered upon a balloon – similar to delivery of a graft. In other variations where the implant comprises a plurality of flexible

and/or hinged panels, it may be delivered in a fashion identical to the approach to valve body delivery described directly below.

[0028] Specifically, in delivering a prosthetic valve assembly as described in US Publication No. 2005/0203614, after advancing the subject delivery system over the guidewire to the treatment location, its outer sheath is retracted to expose the delivery tube. The gripper provided is then rotated relative to the delivery tube (or the delivery tube rotated relative to the gripper) to cause folded segments of the prosthetic valve to uncurl and to extend radially outward through longitudinal slots of the delivery tube. The delivery tube is then retracted (or the gripper advanced) to cause the prosthetic valve (restrained by the fingers) to advance distally out of the delivery tube. The gripper is then retracted relative to the prosthetic valve, releasing the prosthetic valve into the treatment location. Preferably, the inverted segments then revert to the expanded state, causing the valve to lodge against the internal surface of the body lumen (e.g., the aortic valve root or another biologically acceptable aortic position). Additional expansion of the prosthetic valve may be provided, if needed, by a suitable expansion member, such as an expansion balloon or an expanding mesh member (described elsewhere herein), carried on the delivery catheter or other carrier.

[0029] In other methods, different types of prosthetic valves are delivered and deployed within the docking sleeve. In any case, either the valve body or the lumen of the docking sleeve (or both) may be specially adapted to provide a secure interface between the members. Such adaptation may involve complementary VELCRO type hooks, protrusions, tines and loops, dimples, lattice spaces and/or cutouts. Otherwise, a frictional type interface or an interference fit may hold the bodies together. Another means for securing the relative position of the members involves magnets. A plurality of discrete magnetic and/or ferromagnetic elements may be provided. Otherwise, one or both members may be at least partially constructed with magnetic impregnated material (such as polymeric sheet).

[0030] Common to all of the approaches, in accordance with another possibly independent aspect of the invention, is the manner in which a large portion or the entirety of the axial length of the implant is engaged with the docking sleeve. The preferred valve body variations have an axial length in which the valve leaflets are set. These "high walls" may help protect the leaflets (especially when closed-wall valve body structures are provided) and offer an advantageous docking member interface in terms of lateral stability as well as providing significant surface area for sturdy frictional, interlocking or other types of engagement between the members. Since the valve body will not be sutured to the docking sleeve (either an inner or outer portion

thereof – as applicable) maximizing such contact, while still minimizing device size to aid in deliverability, can be important in providing a secure structure able to handle many millions of cycles of pulsing blood pressure.

[0031] Regarding the construction of the docking sleeve, its construction may substantially follow that in the '614 application for its valve bodies. Materials and assembly approaches for providing various "tri-star" and other types of docking sleeves configured as valve bodies presented in the '614 application are specifically contemplated. In some instances, the construction approaches will be modified to provide double-walled, double-cylinder or double-shelled valve docking/retention sleeves as provided herein. With such an endpoint in mind, those with skill in the art can apply the relevant teachings. Generally speaking, the valve body is polymeric, NiTi alloy (where the Af is set for superelastic or SMA use), Beta Titanium alloy, or another suitable biocompatible material or another material with a robust biocompatible coating.

[0032] However constructed, it may be desirable to utilize largely closed or uninterrupted sleeve walls to avoid inward migration of native leaflets that can damage the prosthetic leaflets. In other instances, it may be desirable to strategically locate open sections in the sleeve walls to accommodate nested inner and outer portions without overlapping material. Stated otherwise, use of nesting cylinders/shells will avoid overlap resulting in thicker wall sections that can be more difficult to manipulate into a reduce cross-section profile; or stack-up in size making fit within a percutaneous delivery system difficult.

[0033] In the latter case, overall valve system patency can be ensured by coordinating the valvular body configuration with the docking sleeve configuration so that holes provided in the outer member of the docking sleeve pair are covered or spanned when the valve body is set in place.

[0034] FIGs. 4A-B are axial cross-sectional and perspective views, respectively, depicting another exemplary embodiment of docking sleeve 102 having inner sleeve 114 and outer sleeve 115. FIG. 4A depicts sleeve 102 during deployment. Here, outer sleeve 115 has an aperture 126 configured to receive inner sleeve 114 (which can also be valve support structure 106). Inner sleeve 114 is coupled to outer sleeve 115 by way of a sealing device, which in this embodiment is a fabric 128. Inner sleeve 114 can be positioned within aperture 128 to prevent stack-up of the two sleeves 114 and 115 (i.e., an overlap between the sleeves 114 and 115 that increases the overall wall thickness). FIG. 4B depicts this embodiment while in the tri-star configuration. Fabric 128 is not shown.

[0035] In certain methods according to the present invention, the docking sleeve and valve body may be delivered simultaneously. Such an approach avoids the need for temporary valve approaches as described above. In yet another approach, the devices (i.e., the docking sleeve and valve member) are situated in series on a single delivery guide to allow for rapid, sequential deployment utilizing the same delivery device.

[0036] In another aspect of the method, the size of each of the prosthetic valve body and docking sleeve may be determined in various ways. Techniques described in U.S. Patent Application Serial No. 11/420,189 entitled, "Assessment of Aortic Heart Valve to Facilitate Repair or Replacement," filed May 24, 2006, may be helpful in this regard. Based on such measurement, appropriately sized docking sleeve and valve bodies may be selected for a given patient from stock or an organized panel of different-sized prostheses.

[0037] Various exemplary embodiments of the invention are described below. Reference is made to these examples in a non-limiting sense. They are provided to illustrate more broadly applicable aspects of the invention. Various changes may be made to the invention described and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention. Further, as will be appreciated by those with skill in the art that each of the individual variations described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present inventions. All such modifications are intended to be within the scope of the appended claims.

[0038] Any of the devices described for carrying out the subject methods may be provided in packaged combination for use in executing the method(s). These supply "kits" may further include instructions for use and be packaged in sterile trays or containers as commonly employed for such purposes.

[0039] The invention includes methods that may be performed using the subject devices. The methods may all comprise the act of providing such a suitable device. Such provision may be performed by the end user. In other words, the "providing" act merely requires the end user obtain, access, approach, position, set-up, activate, power-up or otherwise act to provide the requisite device in the subject method. Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events.

[0040] Exemplary aspects of the invention, together with details regarding material

selection and manufacture have been set forth above. As for other details of the present invention, these may be appreciated in connection with the above-referenced patents and publications as well as generally know or appreciated by those with skill in the art. For example, one with skill in the art will appreciate that a lubricious coating (e.g., hydrophilic polymers such as polyvinylpyrrolidone-based compositions, fluoropolymers such as tetrafluoroethylene, hydrophilic gel or silicones) may be used in connection with the devices, if desired, to facilitate low friction manipulation or advancement to the treatment site. The same may hold true with respect to method-based aspects of the invention in terms of additional acts as commonly or logically employed.

[0041] In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention. Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. In addition, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention.

[0042] Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "an," "said," and "the" include plural referents unless the specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[0043] Without the use of such exclusive terminology, the term "comprising" in the claims shall allow for the inclusion of any additional element – irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth n the claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

[0044] The breadth of the present invention is not to be limited to the examples provided and/or the subject specification, but rather only by the scope of the claim language.

CLAIMS

What is claimed is:

1. A medical apparatus, comprising:

a prosthetic valve support structure; and

a docking sleeve configured to interface with the support structure and configured for implantation within a blood vessel of a patient.

2. The medical apparatus of claim 1, wherein the docking sleeve is configured to displace the native anatomy.

3. The medical apparatus of claim 1, wherein the docking sleeve is configured to provide a seal with the native anatomy.

4. The medical apparatus of claim 1, wherein the docking sleeve is configured to anchor against the native anatomy.

5. The medical apparatus of claim 1, wherein the docking sleeve comprises a tissue graft.

6. The medical apparatus of claim 5, wherein the docking sleeve is configured to conform to the native anatomy.

7. The medical apparatus of claim 6, wherein the native anatomy comprises an at least partially calcified valve leaflet.

8. The medical apparatus of claim 6, wherein the docking sleeve has a variable thickness.

9. The medical apparatus of claim 8, wherein the docking sleeve is configured to conform to the aortic sinus.

10. The medical apparatus of claim 8, wherein the docking sleeve has an inner lumen with a regular cross-sectional shape.

11. The medical apparatus of claim 6, further comprising:

an elongate member;

an expandable member coupled with the elongate member, the expandable member configured to deploy the docking sleeve.

12. The medical apparatus of claim 11, further comprising a prosthetic valve coupled with the valve support structure.

13. The medical apparatus of claim 11, wherein the docking sleeve is configured to

transition from an undeployed state suitable for advancement through the vasculature of a patient to a deployed state.

14. The medical apparatus of claim 1, wherein the docking sleeve is compliant.

15. The medical apparatus of claim 14, wherein the docking sleeve is sponge-like.

16. The medical apparatus of claim 1, wherein the docking sleeve comprises an inner sleeve and an outer sleeve.

17. The medical apparatus of claim 16, wherein the docking sleeve further comprises a spring member coupled between the inner sleeve and the outer sleeve.

18. The medical apparatus of claim 17, wherein the spring member is configured to exert a force between the inner sleeve and the outer sleeve to cause the outer sleeve to at least partially conform to the native anatomy.

19. The medical apparatus of claim 18, wherein the spring member is configured to exert a force between the inner sleeve and the outer sleeve to cause the outer sleeve to conform to the native anatomy.

20. The medical apparatus of claim 18, further comprising a sealing member configured to seal a space between the inner and outer sleeves.

21. The medical apparatus of claim 18, wherein the inner and outer sleeves are configured to transition from an undeployed state suitable for advancement through the vasculature of a patient to a deployed state.

22. The medical apparatus of claim 18, wherein the spring member is one of a group comprising the following: a coil spring, a torsion spring, a zig-zag spring, and a balloon.

23. The medical apparatus of claim 18, wherein the spring member comprises air.

24. The medical apparatus of claim 18, wherein the spring member is configured to center the inner sleeve.

25. The medical apparatus of claim 18, wherein the spring member is a first spring member and wherein the docking sleeve further comprises a second spring member coupled between the inner sleeve and the outer sleeve.

26. The medical apparatus of claim 16, wherein the inner sleeve comprises a plurality of hinges.

27. The medical apparatus of claim 16, wherein the outer sleeve comprises a plurality of hinges.

28. The medical apparatus of claim 16, wherein the inner sleeve comprises a

plurality of deflectable panels.

29. The medical apparatus of claim 16, wherein the outer sleeve comprises a plurality of deflectable panels.

30. The medical apparatus of claim 16, wherein the inner sleeve is configured to transition from a tri-star configuration.

31. The medical apparatus of claim 16, wherein the outer sleeve is configured to transition from a tri-star configuration.

32. The medical apparatus of claim 16, wherein the outer sleeve comprises an aperture configured to receive the inner sleeve.

33. The medical apparatus of claim 32, wherein the inner sleeve is coupled to the outer sleeve.

34. The medical apparatus of claim 33, wherein the inner sleeve is coupled to the outer sleeve with a sealing member.

35. The medical apparatus of claim 33, wherein the inner sleeve is coupled to the outer sleeve with a flexible member.

36. The medical apparatus of claim 1, wherein the docking sleeve is coupled to the valve support structure by a spring member.

37. The medical apparatus of claim 36, wherein the spring member is configured to exert a force between the valve support structure and the docking sleeve to cause the docking sleeve to at least partially conform to the native anatomy.

38. The medical apparatus of claim 37, wherein the spring member is configured to exert a force between the valve support structure and the docking sleeve to cause the docking sleeve to conform to the native anatomy.

39. The medical apparatus of claim 37, further comprising a sealing member configured to seal a space between the valve support structure and the docking sleeve.

40. The medical apparatus of claim 37, wherein the valve support structure and docking sleeve are each configured to transition from an undeployed state suitable for advancement through the vasculature of a patient to a deployed state.

41. The medical apparatus of claim 37, wherein the spring member is one of a group comprising the following: a coil spring, a torsion spring, a zig-zag spring and an air spring.

42. The medical apparatus of claim 37, wherein the spring member is configured to

center the valve support structure.

43. The medical apparatus of claim 37, wherein the spring member is a first spring member and wherein the docking sleeve further comprises a second spring member coupled between the valve support structure and the docking sleeve.

44. The medical apparatus of claim 1, wherein the valve support structure is configured to transition from a tri-star configuration.

45. The medical apparatus of claim 1, wherein the docking sleeve is configured to transition from a tri-star configuration.

46. The medical apparatus of claim 1, wherein the docking sleeve comprises an aperture configured to receive the valve support structure.

47. The medical apparatus of claim 1, wherein the valve support structure is coupled to the docking sleeve with a sealing member.

48. The medical apparatus of claim 1, wherein the valve support structure is coupled to the docking sleeve with a flexible member.

49. The medical apparatus of claim 1, wherein the docking sleeve is composed of a NiTi alloy.

50. The medical apparatus of claim 1, wherein the valve support structure is composed of a NiTi alloy.

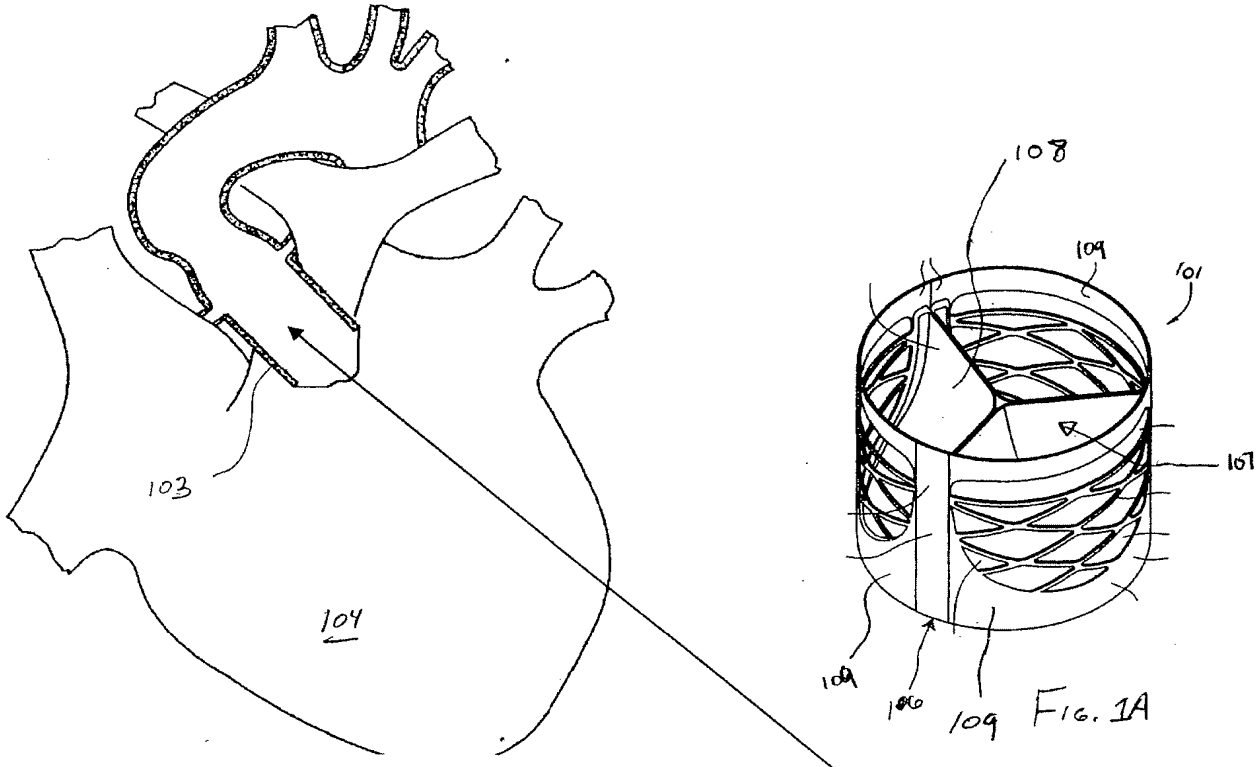
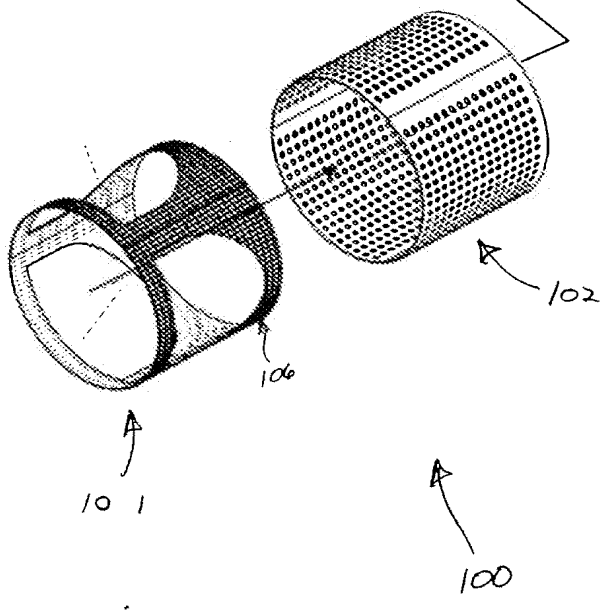


FIG. 1A

FIG. 1B



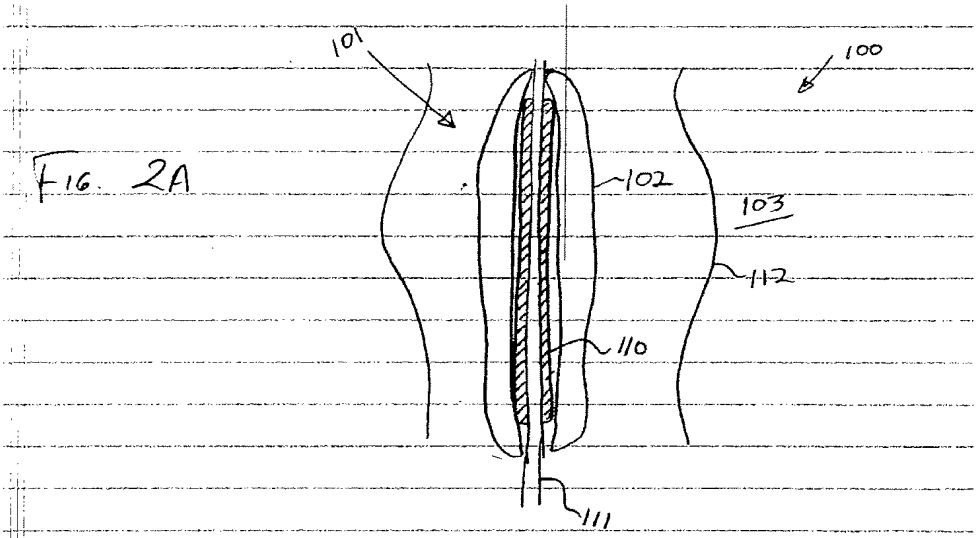


FIG. 2A

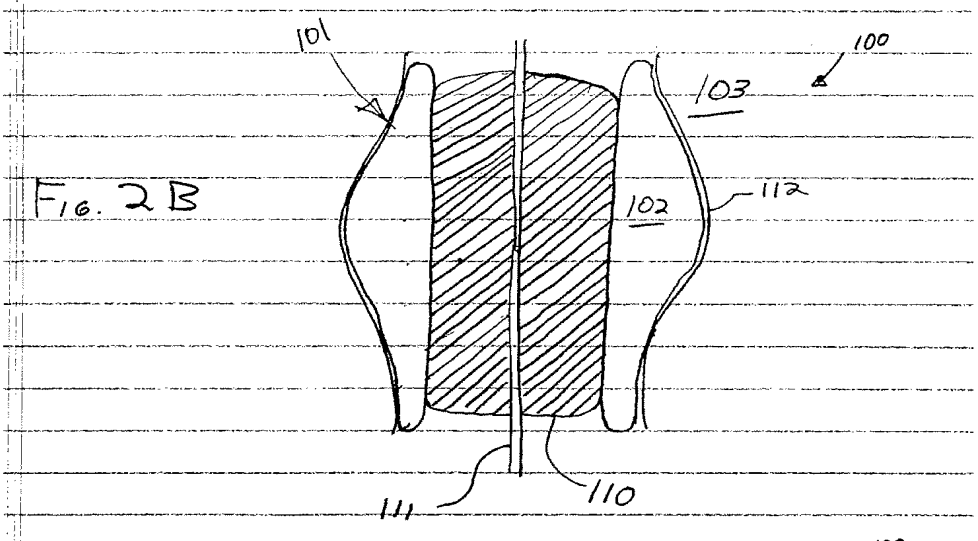


FIG. 2B

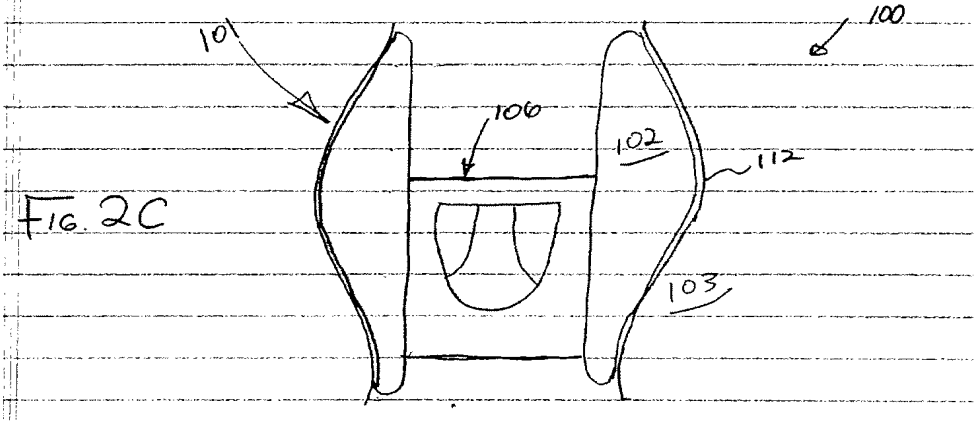


FIG. 2C

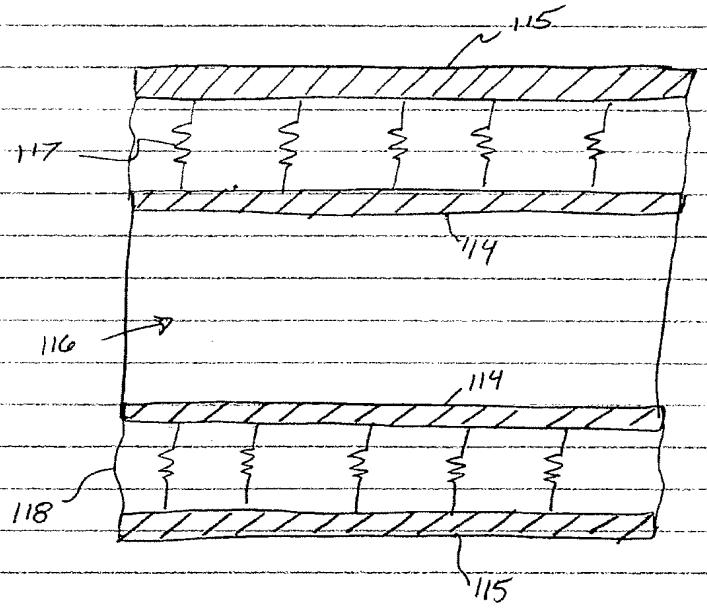

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FIG. 3A

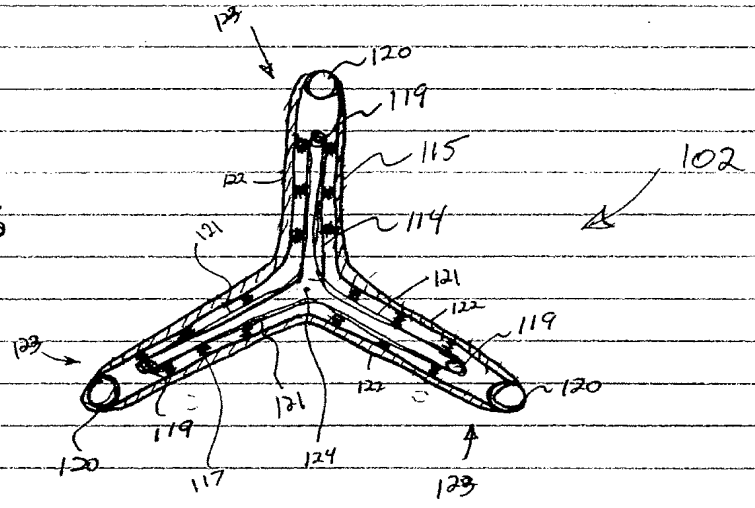
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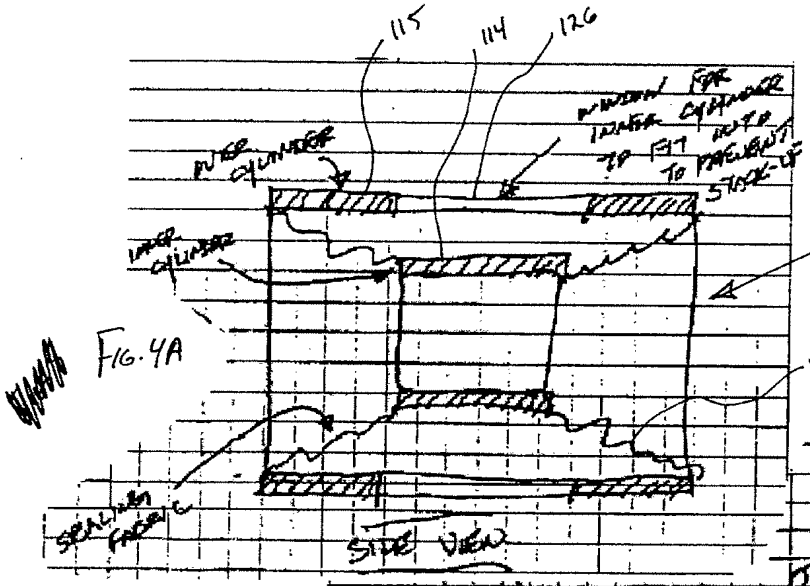
FIG. 3B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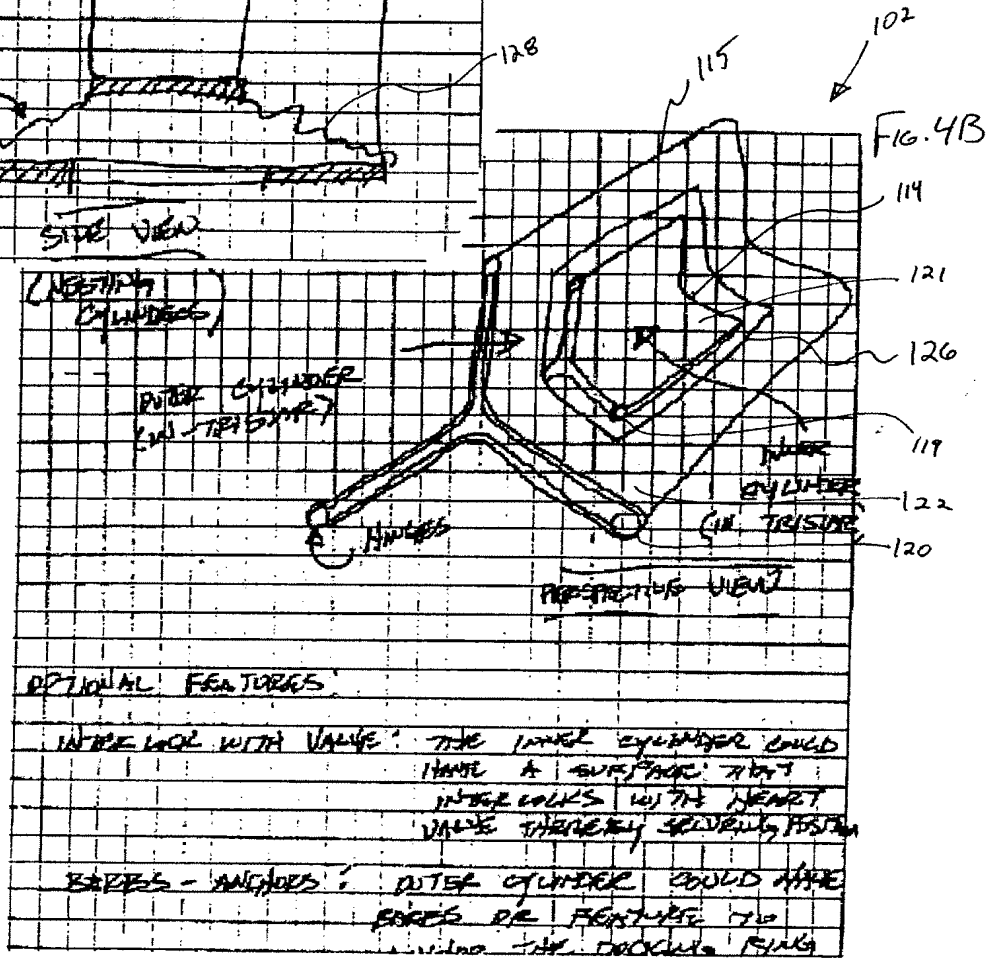
SIDE VIEW

FIG. 4A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OPTIONAL FEATURES:

FIG. 4B

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) **Title:** TWO-STAGE COLLAPSIBLE/EXPANDABLE PROSTHETIC HEART VALVES AND ANCHORING SYSTEMS

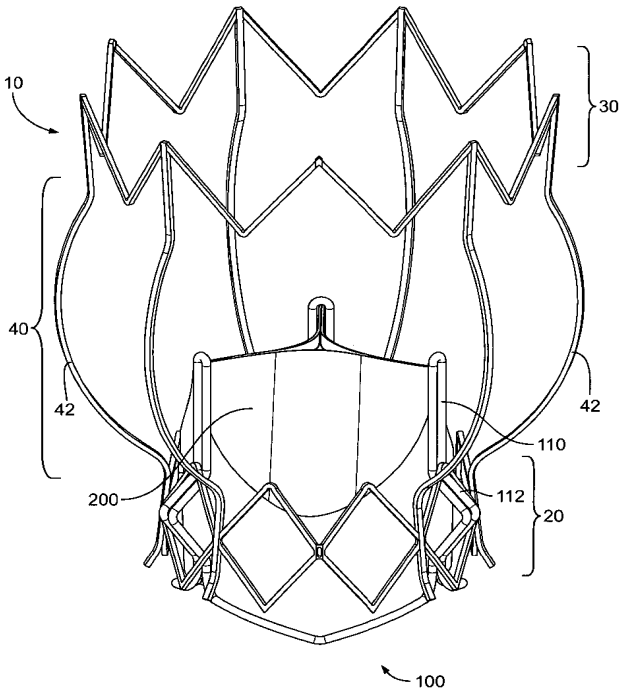


FIG. 1B

(57) Abstract: Prosthetic heart valve apparatus is adapted for delivery into a patient in a circumferentially collapsed condition, followed by circumferential re-expansion at the implant site in the patient. The apparatus includes an annular anchoring structure that can be implanted in the patient first. The apparatus further includes an annular valve support structure, which supports a flexible leaflet structure of the valve. The support and leaflet structures are initially separate from the anchoring structure, but they can be implanted in the patient by interengagement of the support structure with the already-implanted anchoring structure.

WO 2009/045331 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

TWO-STAGE COLLAPSIBLE/EXPANDABLE PROSTHETIC HEART VALVES AND ANCHORING SYSTEMS

[0001] This application claims the benefit of U.S provisional patent application 60/995,812, filed September 28, 2007, which is hereby incorporated by reference herein in its entirety.

Background of the Invention

[0002] This invention relates to collapsible prosthetic heart valves and valve anchoring systems for use in less invasive approaches to heart valve replacement (or at least effective replacement).

[0003] Prosthetic heart valves are known that can be circumferentially collapsed for delivery into a patient via means that are less invasive than full open-chest, open-heart surgery. When such a valve reaches the implant site in the patient, the valve circumferentially re-expands and becomes an operating valve implant in the patient.

[0004] A prosthetic valve of the type described above may need to include a number of concentric layers of material and structure. For example, such a valve typically includes flexible leaflets inside an annular frame structure. Additional layers of material may be

needed for such purposes as buffering (protecting) the leaflets from excessive contact with the frame structure and/or promoting ingrowth of tissue from the patient's surrounding body tissue structures. The frame structure must be strong enough to securely hold the prosthetic valve in place at the implant site in the patient.

[0005] The above requirements for a strong structure and a structure that includes several concentric layers of material can be inconsistent with the desire to circumferentially collapse the prosthetic valve to a relatively small diameter for less invasive delivery into the patient.

Summary of the Invention

[0006] In accordance with certain possible aspects of the invention, a prosthetic heart valve system may be deployed into a patient in two sequential steps. The system includes a collapsible/expandable anchoring platform (frame) and a collapsible/expandable valve with integrated leaflets (tissue, polymer, or other appropriate materials).

[0007] The system works by delivering and deploying (implanting) the anchoring platform first to provide a landing site for the collapsible/expandable valve, which is delivered next. The valve and anchoring platform have interlocking features that facilitate securement of the valve to the already-implanted anchoring platform. The anchoring platform also has features to secure itself to the native anatomy. There are several advantages to this approach that will be described later in this specification.

[0008] One of the desired features for minimally invasive (e.g., percutaneous, transapical, transseptal) approaches is low profile (i.e., relatively small diameter or circumferential size) of the valve/delivery system. Many have attempted to reduce this profile. However, this may result in trade-offs with respect to valve performance. With the two-step approach of this invention, the profile of each system component does not have to be stacked on top of the other. By placing (implanting) the two system components in series, the device (valve, anchoring frame, and delivery system) profiles can be significantly reduced without trade-offs in performance to any of the system components. There are other benefits to this approach that will be highlighted later in this specification.

[0009] Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

Brief Description of the Drawings

[0010] FIG. 1a is a simplified isometric or perspective view of an illustrative embodiment of apparatus in accordance with the invention.

[0011] FIG. 1b is similar to FIG. 1a, but shows the addition of more structure to the apparatus.

[0012] FIG. 2a is a simplified elevational view of an illustrative embodiment of one component from FIGS. 1a and 1b in accordance with the invention.

[0013] FIG. 2b is a simplified, partial, elevational view of the FIG. 2a component from a different angle.

[0014] FIG. 2c is a simplified top view of the component of FIGS. 2a and 2b.

[0015] FIG. 2d is a simplified perspective or isometric view of the component of FIGS. 2a-c.

[0016] FIG. 3a is a view similar to FIG. 2a, but for another illustrative embodiment in accordance with the invention.

[0017] FIG. 3b is a simplified perspective or isometric view of the FIG. 3a structure.

[0018] FIG. 4a is a view similar to FIG. 3a, but for another illustrative embodiment in accordance with the invention.

[0019] FIG. 4b is a simplified, partial, elevational view of the FIG. 4a structure from a different angle.

[0020] FIG. 4c is a simplified perspective or isometric view of the structure shown in FIGS. 4a and 4b.

[0021] FIG. 5a is a simplified perspective or isometric view of a structure like that shown in FIG. 2a in another operating condition in accordance with the invention.

[0022] FIG. 5b is a simplified, partial, elevational view of what is shown in FIG. 5a.

[0023] FIG. 5c is a simplified elevational view of the FIGS. 5a-b structure from another angle.

[0024] FIG. 5d is a simplified top view of the FIGS. 5a-c structure.

[0025] FIG. 6a is a simplified isometric or perspective view of an illustrative embodiment of another component from FIGS. 1a and 1b in accordance with the invention.

[0026] FIG. 6b is another simplified isometric or perspective view of the FIG. 6a structure from another angle.

[0027] FIG. 7a is a view similar to FIG. 6b for another illustrative embodiment in accordance with the invention.

[0028] FIG. 7b is a simplified top view of the structure shown in FIG. 7a.

[0029] FIG. 7c is a simplified, partial, elevational view of the structure shown in FIGS. 7a-b.

[0030] FIG. 8a is a view generally similar to FIG. 1a, but shows an illustrative embodiment of how the FIG. 1a components may be assembled in accordance with the invention.

[0031] FIG. 8b is a simplified elevational view of the FIG. 8a structure, but shows another illustrative embodiment of how the FIG. 1a components may be assembled in accordance with the invention.

[0032] FIG. 9a is similar to FIG. 5a.

[0033] FIG. 9b is similar to FIG. 8a, but shows the structure from another angle.

[0034] FIG. 9c is similar to FIG. 1a, but shows the structure from another angle.

[0035] FIG. 10a is a simplified, partial, elevational view of an illustrative embodiment of use of structure like that shown in FIGS. 3a-b in accordance with the invention.

[0036] FIG. 10b is a view somewhat like FIG. 10a for another illustrative embodiment of the invention.

[0037] FIG. 11a is a simplified perspective or isometric view of an illustrative embodiment of components that can be used in accordance with the invention.

[0038] FIG. 11b is similar to FIG. 11a, but shows the structure from another angle.

[0039] FIG. 11c is a simplified elevational view of the FIGS. 11a-b structure.

[0040] FIG. 11d is similar to FIG. 11c, but shows the structure from another angle.

[0041] FIG. 12a is somewhat like FIG. 11a, but shows an illustrative use of the FIG. 12a structure with an illustrative embodiment of another component in accordance with the invention.

[0042] FIG. 12b is a simplified elevational view of the FIG. 12a structure.

[0043] FIG. 13a is a simplified top view of another illustrative embodiment of a component in accordance with the invention.

[0044] FIG. 13b is a simplified isometric or perspective view of the FIG. 13a structure.

[0045] FIG. 13c is a simplified, partial, isometric or perspective view showing an illustrative use of the FIGS. 13a-b structure in accordance with the invention.

[0046] FIG. 14 is similar to FIG. 6a for an illustrative embodiment with other possible components added.

[0047] FIG. 15 is similar to FIG. 7c for an illustrative embodiment with other possible components added.

Detailed Description

[0047] FIG. 1a shows an illustrative embodiment of an anchoring frame 10 and a valve support frame 100, assembled together, but without any of the other components that a valve in accordance with this invention typically includes. Components 10 and 100 are typically made of a highly elastic metal such as nitinol, but can also be made from stainless steel.

Each of these components may be laser-cut from a tube and then processed to its final shape and dimensions. Each of components 10 and 100 is preferably a continuous annular (ring) structure. Each of components 10 and 100 is annularly, preferably elastically compressible to a smaller annular or circumferential size for delivery into a patient through instrumentation that can be less invasive than full open-chest, open-heart surgery. For example, delivery of the collapsed structures can be through a tube such as a catheter, a trocar, a laparoscopic instrument, or the like. When each component reaches the implant site in the patient, that component can be released to (preferably) elastically re-expand to the approximate size shown in FIG. 1a. This causes the re-expanded component (and any other components carried by that component) to implant itself in the patient. Anchoring structure 10 is delivered into and implanted in the patient first. Then valve support structure 100 (with valve 200 (FIG. 1b) mounted inside it) is delivered into the patient and implanted inside the already-implanted anchoring structure 10.

[0048] Anchoring structure 10 is primarily responsible for holding the valve in place in the patient, in addition to anchoring itself to native anatomy of the patient. Valve support structure 100 includes features that interengage or interlock with features of anchoring structure 10 to hold valve support structure 100 in place relative to anchoring structure 10. In the embodiment shown in FIGS. 1a-b these interlocking features include radial outward projections 112 on the commissure posts 110 of valve support structure 100 fitting into closed-perimeter,

open-center cells 22 in the annulus inflow portion 20 of anchoring structure 10.

[0049] Annulus inflow portion 20 of anchoring structure 10 is typically implanted in or near the patient's native valve annulus. This is the reason for referring to this portion of structure 10 as the annulus inflow portion. ("Inflow" is a term that is used with reference to the direction of blood flow through the prosthetic valve when the valve is in use in a patient. "Outflow" is similarly used with reference to the direction of blood flow through the prosthetic valve.) The embodiment shown in FIGS. 1a-1b is especially adapted for use as a prosthetic aortic valve. Annulus inflow portion 20 is therefore implanted in or near the patient's native aortic valve annulus. An aortic outflow portion 30 of anchoring structure 10 then resides in the patient's aorta. Portions 20 and 30 are connected to one another by connecting strut structure 40, which passes through the patient's valsalva sinus. The connecting struts 42 of structure 40 bulge radially out into the outwardly bulging lobes of the valsalva sinus to help hold the valve in place in the patient.

[0050] Valve or leaflet structure 200 (mounted inside valve support structure 100) typically includes three flexible leaflets that come together to close the valve as shown in FIG. 1b. This occurs when blood pressure above the valve as viewed in FIG. 1b is greater than blood pressure below the valve. When blood pressure below the valve exceeds blood pressure above the valve, the leaflets of the valve are pushed aside to open the valve and allow blood to flow upward through the valve. Suitable materials for leaflets 200

include biological tissue, metal (e.g., thin nitinol), flexible polymers or mesh-reinforced polymers, and the like.

[0051] Again, not all components of a finished and implanted valve are shown in FIG. 1b. For example, other layers of material such as tissue, polymer, fabric, buffer material, or the like can be included for such purposes as cushioning other components, promoting tissue ingrowth, etc.

[0052] FIGS. 2a-d show an illustrative embodiment of a valve support structure 100 by itself from several directions. (FIG. 1b shows only part of that structure.) A possible feature brought out by these FIGS. is the scalloped inflow edge of structure 100. (Again, inflow refers to the direction of blood flow through the valve when in use in a patient.) The anchoring frame 10 may also be similarly scalloped. By "scalloped" it is meant that the inflow edge is relatively high near the base of at least one (preferably all) of the commissures of the patient's native heart valve, and also the commissures 110 of the prosthetic valve. A typical high area is pointed to from the reference letter H. Elsewhere the inflow edge can be relatively low (pointed to from the reference letter L). "High" means that such a portion of the inflow edge is closer to the geometric plane defined by the distal free ends or tips of commissure posts 110. "Low" means that such a portion of the inflow edge is farther from that geometric plane. Making one or more portions of the inflow edge high as described above helps the implanted valve avoid impinging on the patient's native mitral valve and other structures in

the heart that are adjacent the aortic valve (e.g., conduction system pathways and the AV node).

[0053] FIGS. 3a-b show another illustrative embodiment of a valve support structure 100 by itself from different directions. A possible feature brought out by these FIGS. is the provision of what may be called spread elbows for outward projections 112. This means that the two members that make up each commissure post 110 diverge from one another in the annular direction where they extend radially out to form a projection 112. This can help to improve stability of engagement between structures 10 and 100 in an implanted valve.

[0054] FIGS. 3a-b (and also other FIGS.) illustrate the concept that valves of this invention can employ what may be termed independent flexing commissure posts 110. At least above outward projections 112, commissure posts 110 can be free of contact with anchoring structure 10 when components 10 and 100 are interlocked together. Commissure posts 110 are therefore cantilevered to their free end tips and can accordingly flex independently of one another and other stent-like structure (e.g., 10) of the valve. This can help relieve stress on valve structure 200 and has many other potential benefits.

[0055] FIGS. 4a-c show another illustrative embodiment of a valve support structure 100 in accordance with the invention. In this embodiment each commissure post 110 is effectively a single member. Also, the inflow edge is inverted in the up-down direction as compared, for example, to the inflow edge of the structures 100 shown in earlier FIGS.

[0056] FIGS. 5a-d show several views of an annularly or circumferentially compressed or collapsed valve support structure 100 in accordance with the invention. FIG. 5b is only partial, and FIG. 5d is a top view.

[0057] FIGS. 6a-b show two views of an illustrative embodiment of anchoring structure 10 by itself.

[0058] FIGS. 7a-c show several views of an illustrative embodiment of what may be referred to as a short anchoring structure 10. This latter type of anchoring structure includes only annulus inflow portion 20 and truncated struts 42 extending up from annulus inflow portion 20 into a portion of the patient's valsalva sinus.

[0059] FIGS. 8a-b show two ways of implanting component 100 into component 10 in a patient. (Component 10 is assumed to be already implanted at the desired location in the patient.) In FIG. 8a valve frame structure 100 is delivered into anchoring structure 10 from the inflow end of structure 10. In FIG. 8b valve frame 100 is delivered into anchoring structure 10 from the outflow end of structure 10.

[0060] FIGS. 9a-c show an illustrative embodiment of delivery of valve support structure 100 into anchoring structure 10 in accordance with the invention. In FIG. 9a valve support structure 100 is annularly compressed for delivery into the patient. In FIG. 9b structure 100 is released to re-expand as it approaches the inflow end of already-implanted structure 10. In FIG. 9c structure 100 is pushed into structure 10 via the inflow end of structure 10. Structure 100 latches into structure 10 by means of projections 112 on structure 100 projecting radially out into cells 22 in structure 10.

[0061] FIGS. 10a-b show details of the interlocking engagement between outward projections 112 on structure 100 and cells 22 in structure 10. FIG. 10a shows this detail for a spread-elbow embodiment like that shown in FIGS. 3a-b. FIG. 10b shows this detail for another embodiment like that shown in FIGS. 9a-c.

[0062] FIGS. 11a-d provide more information about how valve structure 200 may be mounted in valve support structure or frame 100. The three leaflets of valve structure 200 are identified by reference numbers 210a, b, and c. If desired, a cuff (e.g., of fabric and/or tissue sheet material) can be integrated onto the valve assembly to promote tissue ingrowth and to help seal the valve to prevent perivalvular leakage. See, for example, FIG. 14, which shows an illustrative embodiment of such a cuff 300 secured around the outside of the annulus portion 20 of an anchoring frame 10 like that shown in FIG. 6a. As another example, FIG. 15 shows an illustrative embodiment of a cuff 300 secured around the outside of the annulus portion 20 of a short anchoring structure 10 like that shown in FIG. 7c. In each of FIGS. 14 and 15 the cuff 300 may be secured to the underlying structure (e.g., 10) with suture material 310 that passes through the cuff material and loops around adjacent portions of the frame structure 10. Although FIGS. 14 and 15 show cuff 300 extending annularly around the outside of frame structure 10, an alternative is for cuff 300 to extend annularly around the inside of the frame structure.

[0063] FIGS. 12a-b are two views of illustrative embodiments of the assembly of components 10, 100, 200 when a short anchoring frame 10 like that shown in FIGS. 7a-c is used. FIG. 12b shows the use of spread-

elbow projections 112. FIG. 12a shows the use of projections 112 that do not have the spread-elbow configuration. Thus elbows like 112 can point in the same direction (e.g., as in FIG. 12a) or in opposite directions (e.g., as in FIG. 12b).

[0064] FIGS. 13a-c show a rotate and lock embodiment of a valve support structure 100 in accordance with the invention. In this embodiment each commissure post 110 is effectively a single member and includes a projection 112. As shown in FIG. 13a, projections 112 do not extend radially outwardly perpendicular to a circumference of the annular structure, but rather extend radially out at an angle A that is not a right angle to the circumference. FIG. 13c shows details of the interlocking engagement between angled projections 112 and cells 22 in structure 10. The valve support structure 100 is secured to anchoring structure 10 by using a rotate and lock feature. The valve frame 100 is inserted into the anchoring structure 10 and then rotated in the direction of the angled projections 112 to engage projections 112 with portions of the perimeter of cells 22.

[0065] Recapitulating and extending the foregoing, the following are some of the various possible features and highlights of the invention.

[0066] Two-stage deployment valve system. Valve frame 100 and anchoring frame 10 can be integrated into the same delivery system or can be accomplished using two separate delivery systems.

[0067] Lower profile of the integrated system. Especially lower profile if collapsible/expandable valve 100/200 and anchoring 10 systems are separate.

[0068] Anchoring/docking frame 10 is delivered and deployed first and independent of the valve 100/200.

[0069] The anchoring/docking frame 10 has anchoring features and mechanisms at the inflow edge 20, middle section 40, and the outflow edge 30 to secure it in place and prevent migration. The anchoring/docking frame 10 can also have anchoring sections at the inflow 20 only, middle section 40 only, outflow 30 only, or any combination thereof.

[0070] The anchoring frame 10 will anchor in place using native geometry (patient anatomy) and may remodel that geometry to provide an adequate landing site for the subsequently delivered valve 100/200.

[0071] The collapsed valve 100/200 is delivered second and deployed/expanded within the anchoring structure 10 upon reaching the landing site. The collapsed valve 100/200 can also be expanded just before reaching the anchoring frame 10 and then pushed in to lock.

[0072] The valve 100/200 has feature geometries (e.g., 112) to make it mate and interlock in place within the existing deployed anchoring structure 10.

[0073] The valve 100/200 has independently flexing commissure posts 110 that contribute to prolonged, durable performance by reducing stresses.

[0074] A cuff (e.g., like above-mentioned cuff 300) can be integrated onto the valve frame 100 assembly to aid in sealing in order to prevent perivalvular leaks. Alternatively or in addition, such a cuff 300 can be integrated onto the anchoring frame 10 for similar purposes as shown, for example, in FIG. 14 or 15.

[0075] The valve frame 100 remains in place via the interlocking mechanism 22/112, in addition to its

radial force (frame 100 can be manufactured from memory-shaped nitinol or from stainless steel and then expanded with a balloon).

[0076] The slotted commissure post design (e.g., 110 in FIGS. 1a-b) facilitates leaflet integration by sliding the edges of the leaflets 200 in the inverted U-shaped opening in each post 110 and wrapping around before securing the leaflets to the valve frame 100. Alternatively, for this or other valve frames 100 shown herein, the valve frame may be dipped over specially designed mandrels to create polymeric leaflets that are integral with the frame. In other words, the leaflet structure may be created using a forming process producing polymeric leaflets that are integral with the valve support structure.

[0077] The symmetry of expanded frame cells 22 at the lower band (inflow side) 20 of the anchoring frame 10 allows freedom in valve radius orientation because the valve frame (stent) elbows 112 can interlock with any of the expanded cells 22.

[0078] In other embodiments, if rotational alignment between the valve 100/200 and the anchoring frame 10 is desired, a suture line (nitinol wire or any other appropriate member material) pre-attached to the valve 100/200 and running into corresponding and desired cell 22 locations in the anchoring frame can be used. The suture line can be used to guide the valve 100/200 as it is being advanced; and once at the desired location, the valve 100/200 can be deployed and the holding/retaining line can be removed. Upon deployment, the suture line can be cut and removed.

[0079] A sealing cuff (e.g., like 300) can be

incorporated on the valve frame 100, the anchoring frame 10, or both, to prevent leakage.

[0080] Other interlocking concepts/geometries between the valve frame 100 and anchoring frame 10 are possible and can be employed. What has been presented is an example.

[0081] The contour/geometry of the interlocking cell 22 in the anchoring frame 10 can be of different geometries that would also adapt, mate, and interlock with corresponding shapes 112 on the valve frame 100.

[0082] The short anchoring frame embodiment (e.g., FIGS. 7a-c) has capabilities in anchoring using barbs 44 on the inflow end, using its outward bias radial force, and using elongated barbs 42 (straight or curved) on the outflow end. The elongated barbs 42 have a dual function (anchoring by engaging native calcified leaflets and holding those leaflets radially outwardly, away, and clear to prevent interference with new valve function). Another embodiment may have the barbs 42 connected together on the outflow end, allowing shorter sections to engage the native leaflets. The height of the short frame 10 can be short enough so it does not interfere with blood perfusion into the patient's coronary arteries.

[0083] The anchoring frame 10 can be self-expanding or balloon expandable. The valve frame 100 can also be self-expanding or balloon expandable.

[0084] The delivery system used in accordance with the invention can have both scenarios integrated in series or a desired combination of self- and balloon-expanding mechanisms.

[0085] The invention provides the ability to precisely size the valve frame 100 once the anchoring

frame 10 is deployed (in the case of separate systems). Once the anchoring frame 10 is in place, the opening can be sized (measured, e.g., fluoroscopically) and the appropriate valve 100/200 size can be selected to be expanded and implanted within the anchoring frame 10.

[0086] Restating at least some of the foregoing in terms that may to some extent be different from terms used at other points in this specification, apparatus for use as a prosthetic heart valve may include an annular anchoring structure (e.g., 10) that is adapted for (1) delivery into a patient in a circumferentially collapsed condition, and (2) circumferential re-expansion and anchoring engagement with tissue of the patient when at an implant site in the patient. The apparatus may further include an annular valve support structure (e.g., 100) that is initially separate from the anchoring structure 10 and that is adapted for (1) delivery into the patient in a circumferentially collapsed condition, and (2) circumferential re-expansion and interengagement with the anchoring structure when adjacent to the anchoring structure in the patient. The apparatus may still further include a flexible leaflet structure (e.g., 200) disposed inside the valve support structure.

[0087] The above-mentioned anchoring structure 10 may include a plurality of closed-perimeter, open-center cells (e.g., 22) disposed in an array that extends annularly (circumferentially) around the anchoring structure.

[0088] The above-mentioned valve support structure 100 may include a plurality of projections (e.g., 112), each of which can extend radially

outwardly into a respective one of the above-mentioned cells 22.

[0089] The above-mentioned valve support structure 100 may include a plurality of circumferentially spaced commissure post structures (e.g., 110). Each of the above-mentioned projections 112 may be on a respective one of the commissure post structures.

[0090] Each of the above-mentioned projections 112 may include first and second inclined surfaces (e.g., 113a and 113b in FIG. 4a) that meet at a radially outermost peak (e.g., 113c in FIG. 4a). The first inclined surface 113a may incline from the peak 113c radially inwardly in a direction toward an inflow end of the apparatus (e.g., toward the bottom as viewed in FIG. 4a). The second inclined surface 113b may incline from the peak 113c radially inwardly in a direction toward an outflow end of the apparatus (e.g., toward the top as viewed in FIG. 4a).

[0091] Each of the above-mentioned projections 112 and the respective cell 22 into which that projection can extend may be sized so that the first inclined surface 113a can contact a first portion (e.g., 23a in FIG. 6b) of the perimeter of the cell that is toward the inflow end of the apparatus, and also so that, at the same time, the second inclined surface 113b can contact a second portion (e.g., 23b in FIG. 6b) of the perimeter of the cell that is toward the outflow end of the apparatus. Interlocking features of this kind help prevent relative movement between frames 10 and 100 after those components have interlocked. (As used in contexts like this, "contact" may mean either direct contact or contact that is transmitted through one or

more intervening layers of other material such as fabric, tissue, or the like.)

[0092] Each of the above-mentioned projections 112 may further include third and fourth inclined surfaces (e.g., 113d and 113e in FIG. 3a) that meet at a radially outermost peak (e.g., 113f in FIG. 3a). The third and fourth surfaces 113d and 113e and the second peak 113f may be circumferentially spaced from the first and second inclined surfaces 113a and 113b and the first peak 113c, respectively (e.g., as shown in FIG. 3a, or as shown in FIG. 5b). The third inclined surface 113d may incline from the second peak 113f radially inwardly in a direction toward the inflow end (e.g., toward the bottom in FIG. 3a), and the fourth inclined surface 113e may incline from the second peak 113f radially inwardly in a direction toward the outflow end (e.g., toward the top in FIG. 3a).

[0093] Each of the above-mentioned projections 112 and the respective cell 22 into which that projection can extend may be sized so that all four of the above-mentioned inclined surfaces 113a, 113b, 113d, and 113e can, at the same time, contact respective portions of the perimeter of the cell (see, for example, FIG. 10a where such four cell perimeter portions are identified as 25a, 25b, 25d and 25e). Two of these cell perimeter portions 25a and 25d are toward the inflow end (e.g., toward the bottom in FIG. 10a), and the other two cell perimeter portions 25b and 25e are toward the outflow end (e.g., toward the top in FIG. 10a).

[0094] In each of the above-mentioned projections 112, the first and third inclined surfaces 113a and 113d may diverge from one another toward the first and second peaks 113c and 113f (e.g.,

as shown in FIG. 3a). The same may be true of the second and fourth inclined surfaces 113d and 113e. This gives a projection 112 a spread elbow configuration as described elsewhere in this specification.

[0095] The above-mentioned first and third cell perimeter portions 25a and 25d may meet at a point (e.g., 27a in FIG. 10a) and may incline away from one another toward the outflow end (e.g., toward the top in FIG. 10a). The above-mentioned second and fourth cell perimeter portions 25b and 25e may similarly meet at a point (e.g., 27b in FIG. 10a) and may incline away from one another toward the inflow end (e.g., toward the bottom in FIG. 10a).

[0096] The above-mentioned anchoring structure 10 may include a plurality of members (e.g., 44 in FIG. 13c) that are adapted (e.g., as a result of resilient bias) to incline radially outwardly on an inflow side of the patient's native heart valve annulus at the implant site. Alternatively or in addition, the anchoring structure 10 may include a plurality of members (e.g., 42) that are adapted (e.g., as a result of resilient bias) to incline radially outwardly on an outflow side of the patient's native heart valve annulus at the implant site. In such a case, the members 42 may be adapted to push radially outwardly on the patient's native heart valve leaflets at the implant site.

[0097] The above-mentioned anchoring structure 10 may be resiliently biased to circumferentially re-expand. Alternatively or in addition, the above-mentioned valve support structure 100 may be resiliently biased to circumferentially re-expand.

[0098] The above-mentioned anchoring structure 10 may include an annular annulus inflow portion (e.g., 20) adapted for interengagement with the valve support structure 100. Anchoring structure 10 may further include an annular aortic outflow portion (e.g., 30) adapted for disposition in the patient's aorta downstream from the patient's native aortic valve at the implant site. Anchoring structure 10 may still further include at least one connecting strut (e.g., 42) extending between and connecting the annulus inflow portion 20 and the aortic outflow portion 30.

[0099] A method of implanting a prosthetic heart valve in a patient may include implanting an annular anchoring structure (e.g., 10) in the patient by delivering the anchoring structure into the patient in a circumferentially collapsed condition and then circumferentially expanding the anchoring structure while in the patient to implant the anchoring structure at an implant site in the patient. The method may further include delivering an annular valve support structure (e.g., 100), which is initially separate from the anchoring structure 10, into the patient in a circumferentially collapsed condition. The method may still further include circumferentially expanding the valve support structure 100 while in the patient, and interlocking the expanded valve support structure with the implanted anchoring structure 10.

[0100] A method like the above may employ inserting the valve support structure 100 into the implanted anchoring structure 10 in the direction that blood will flow through the implanted valve. Alternatively, the method may employ inserting the valve support structure 100 into the implanted anchoring structure 10

in a direction that is opposite to the above-mentioned bloodflow direction.

[0101] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, instead of both of components 10 and 100 being elastically compressible and re-expandable, either or both of those components may be plastically compressible and re-expandable. Such plastic re-expansion may be, for example, by inflation of a balloon catheter temporarily inserted inside the component to be plastically re-expanded.

The Invention Claimed Is:

1. Apparatus for use as a prosthetic heart valve comprising:

an annular anchoring structure that is adapted for (1) delivery into a patient in a circumferentially collapsed condition, and (2) circumferential re-expansion and anchoring engagement with tissue of the patient when at an implant site in the patient;

an annular valve support structure that is initially separate from the anchoring structure and that is adapted for (1) delivery into the patient in a circumferentially collapsed condition, and (2) circumferential re-expansion and interengagement with the anchoring structure when adjacent to the anchoring structure in the patient; and

a flexible leaflet structure disposed inside the valve support structure.

2. The apparatus defined in claim 1 wherein the anchoring structure comprises a plurality of closed-perimeter, open-center cells disposed in an array that extends annularly around the anchoring structure.

3. The apparatus defined in claim 2 wherein the valve support structure comprises a plurality of projections, each of which can extend radially outwardly into a respective one of the cells.

4. The apparatus defined in claim 3 wherein the valve support structure comprises a plurality of circumferentially spaced commissure post structures,

and wherein each of the projections is on a respective one of the commissure post structures.

5. The apparatus defined in claim 4 wherein each of the projections comprises first and second inclined surfaces that meet at a radially outermost peak, the first inclined surface inclining from the peak radially inwardly in a direction toward an inflow end of the apparatus, and the second inclined surface inclining from the peak radially inwardly in a direction toward an outflow end of the apparatus.

6. The apparatus defined in claim 5 wherein each of the projections and the respective cell into which that projection can extend are sized so that the first inclined surface can contact a first portion of the perimeter of the cell that is toward the inflow end of the apparatus, and at the same time the second inclined surface can contact a second portion of the perimeter of the cell that is toward the outflow end of the apparatus.

7. The apparatus defined in claim 6 wherein each of the projections further comprises third and fourth inclined surfaces that meet at a radially outermost second peak, the third and fourth inclined surfaces and the second peak being circumferentially spaced from the first and second inclined surfaces and the peak, respectively, the third inclined surface inclining from the second peak radially inwardly in a direction toward the inflow end, and the fourth inclined surface inclining from the second peak radially inwardly in a direction toward the outflow end.

8. The apparatus defined in claim 7 wherein each of the projections and the respective cell into which that projection can extend are further sized so that the third inclined surface can contact a third portion of the perimeter of the cell that is toward the inflow end at the same time that the first inclined surface can contact the first portion, and so that, at that same time, the fourth inclined surface can contact a fourth portion of the perimeter of the cell that is toward the outflow end.

9. The apparatus defined in claim 8 wherein, in each of the projections, the first and third inclined surfaces diverge from one another toward the peak and the second peak, and the second and fourth inclined surfaces also diverge from one another toward the peak and the second peak.

10. The apparatus defined in claim 9 wherein the first and third portions meet at a first point and incline away from one another toward the outflow end, and wherein the second and fourth portions meet at a second point and incline away from one another toward the inflow end.

11. The apparatus defined in claim 1 wherein the anchoring structure comprises a plurality of members that are resiliently biased to incline radially outwardly on an inflow side of the patient's native heart valve annulus at the implant site.

12. The apparatus defined in claim 1 wherein the anchoring structure comprises a plurality of members that are resiliently biased to incline radially

outwardly on an outflow side of the patient's native heart valve annulus at the implant site.

13. The apparatus defined in claim 12 wherein the members are adapted to push radially outwardly on the patient's native heart valve leaflets at the implant site.

14. The apparatus defined in claim 1 wherein the anchoring structure is resiliently biased to circumferentially re-expand.

15. The apparatus defined in claim 1 wherein the valve support structure is resiliently biased to circumferentially re-expand.

16. The apparatus defined in claim 1 wherein the anchoring structure comprises:

an annular annulus inflow portion adapted for inter-engagement with the valve support structure;

an annular aortic outflow portion adapted for disposition in the patient's aorta downstream from the patient's native aortic valve at the implant site; and

a least one connecting strut extending between and connecting the annulus inflow portion and the aortic outflow portion.

17. The apparatus defined in claim 1 wherein the leaflet structure comprises a leaflet made of a material selected from the group consisting of biological tissue, metal, polymers, and mesh-reinforced polymers.

18. The apparatus defined in claim 1 wherein the leaflet structure is created using a forming process producing polymeric leaflets that are integral with the valve support structure.

19. The apparatus defined in claim 1 further comprising:

an annular cuff structure secured to at least one of the anchoring structure and the valve support structure.

20. A method of implanting a prosthetic heart valve in a patient comprising:

implanting an annular anchoring structure in the patient by delivering the anchoring structure into the patient in a circumferentially collapsed condition and then circumferentially expanding the anchoring structure while in the patient to implant the anchoring structure at an implant site in the patient;

delivering an annular valve support structure, which is initially separate from the anchoring structure, into the patient in a circumferentially collapsed condition;

circumferentially expanding the valve support structure while in the patient; and

interlocking the expanded valve support structure with the implanted anchoring structure.

21. The method defined in claim 20 wherein the prosthetic heart valve is implanted in the patient so that blood will flow through it in a bloodflow direction, and wherein the method further comprises:

inserting the valve support structure into the implanted anchoring structure in the bloodflow direction.

22. The method defined in claim 20 wherein the prosthetic heart valve is implanted in the patient so that blood will flow through it in a bloodflow direction, and wherein the method further comprises:

inserting the valve support structure into the implanted anchoring structure opposite the bloodflow direction.

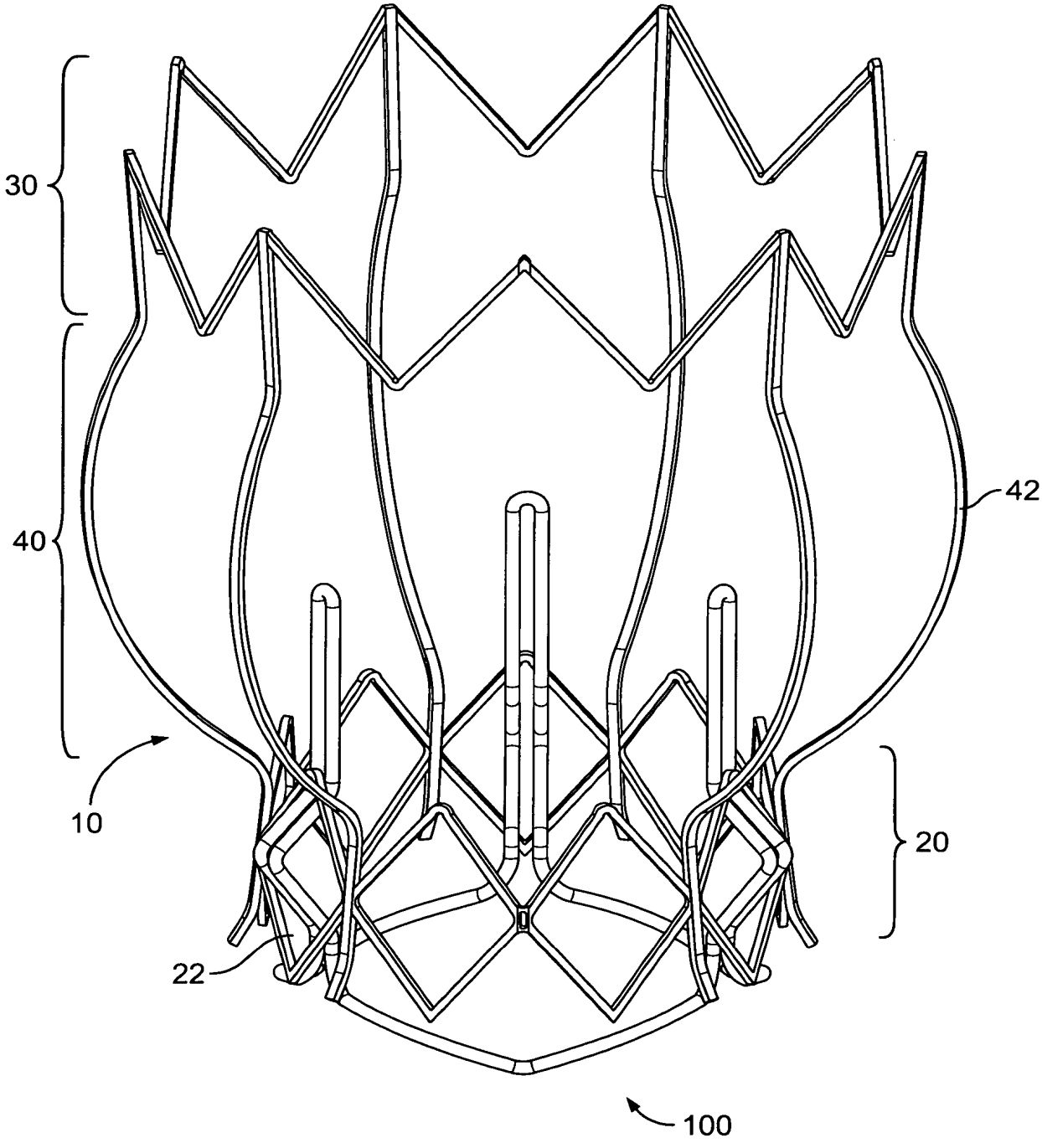


FIG. 1A

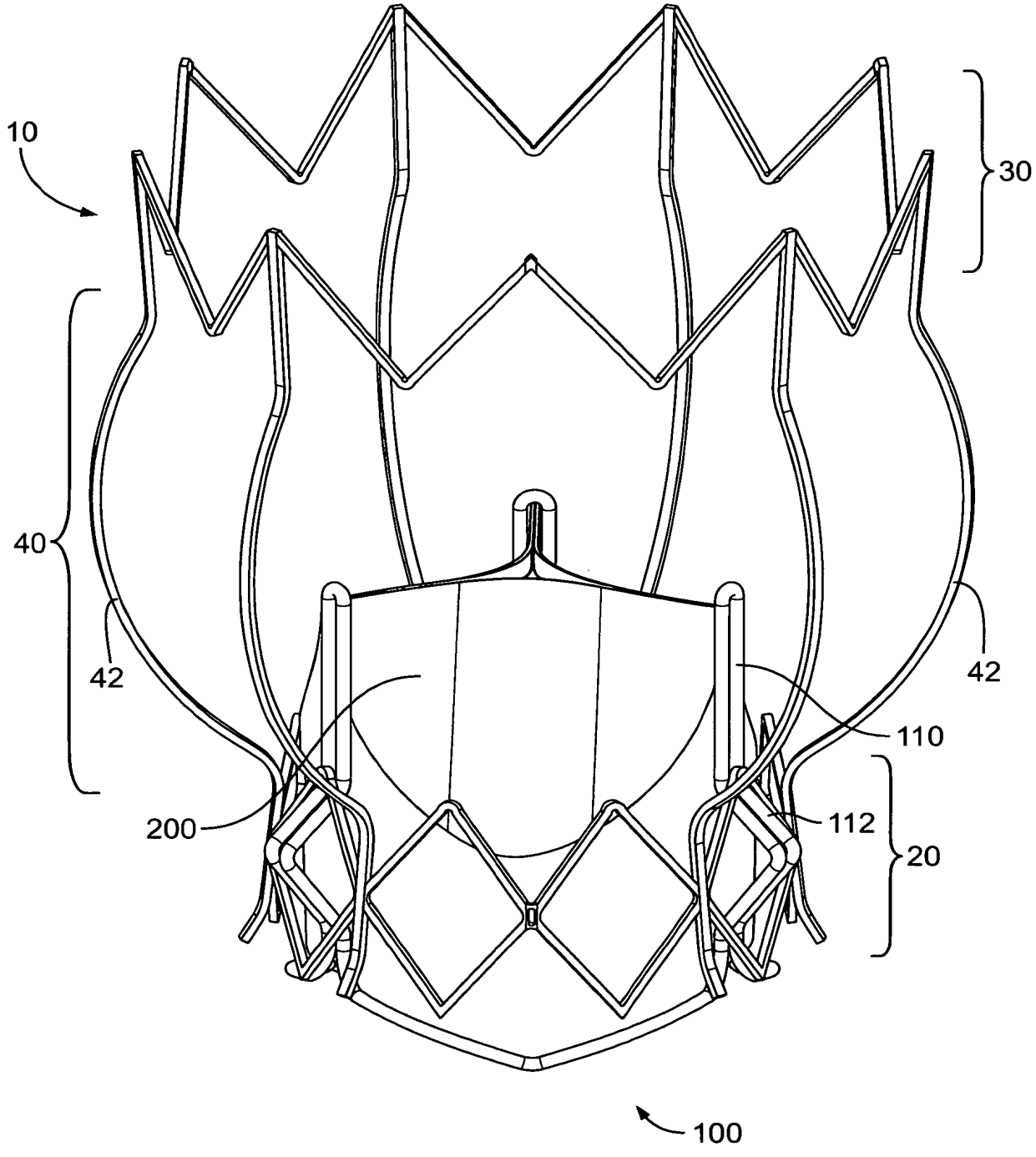


FIG. 1B

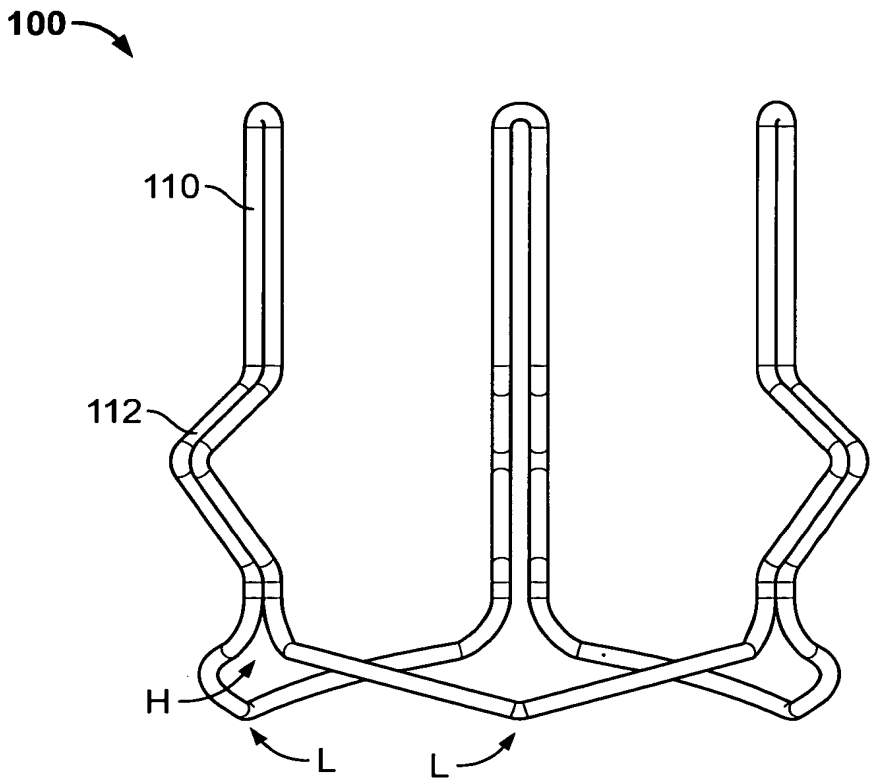


FIG. 2A

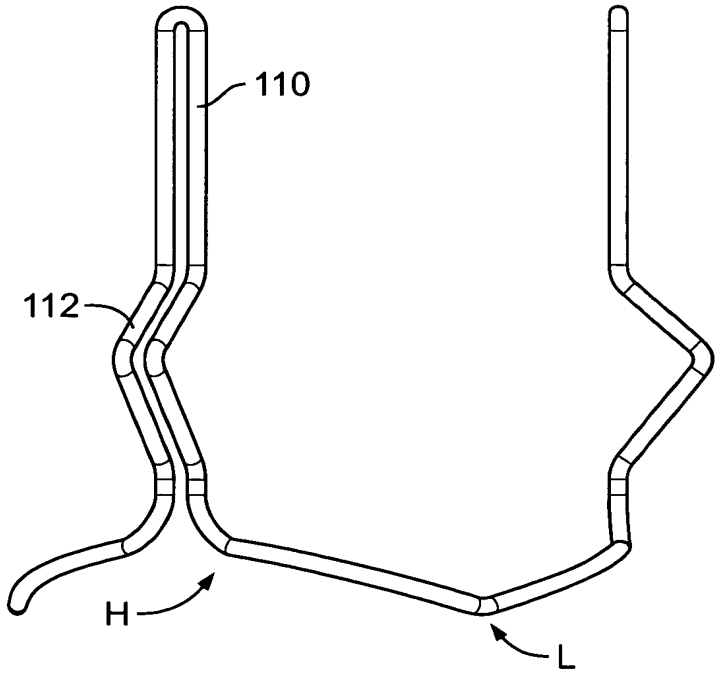


FIG. 2B

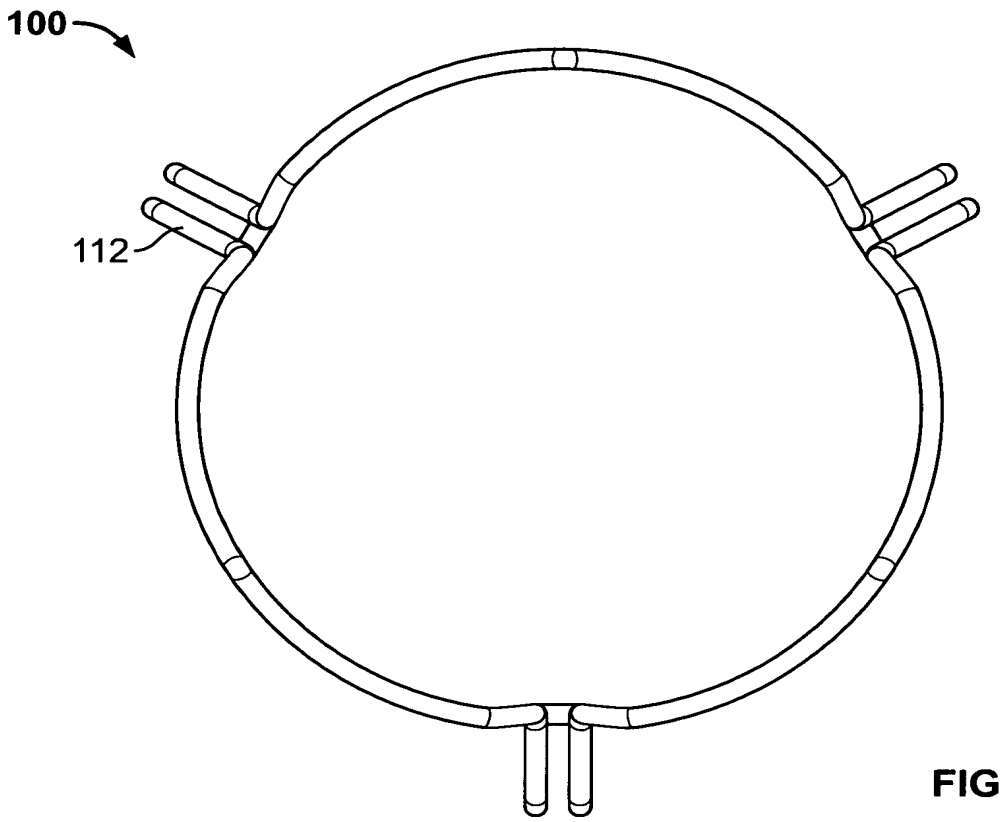


FIG. 2C

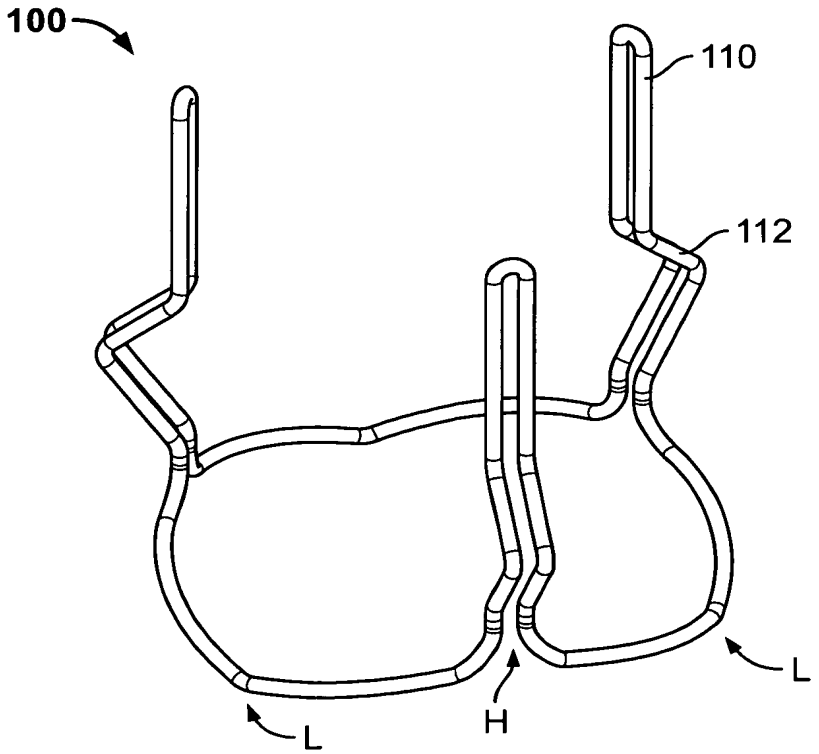
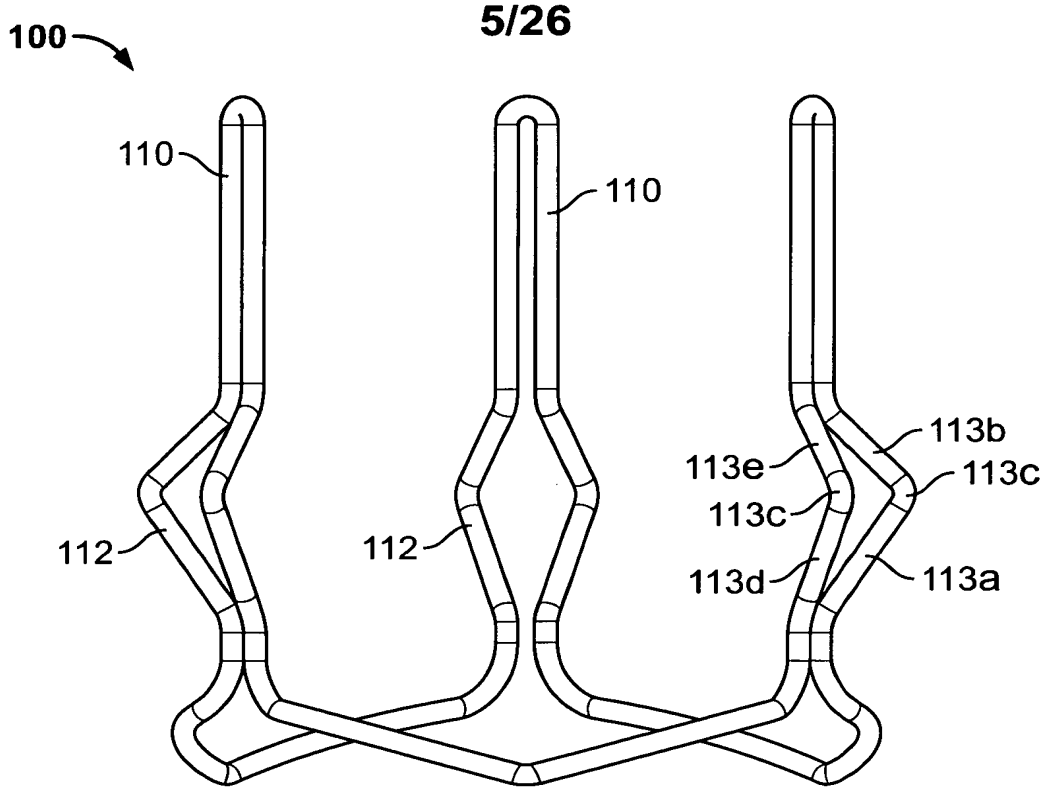


FIG. 2D


100
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113b
113e
113c
113c
113d
113a

FIG. 3A

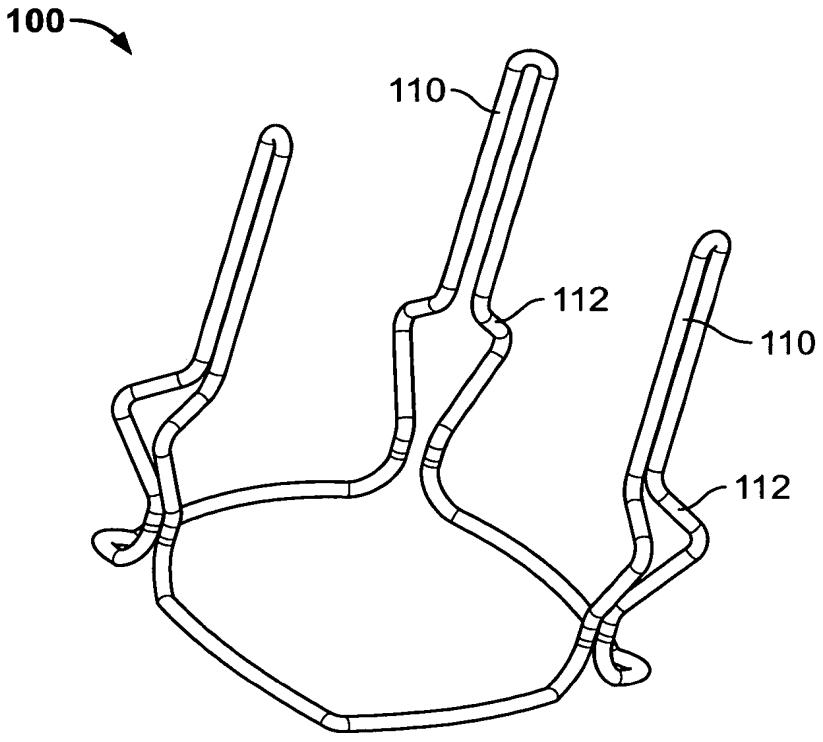
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FIG. 3B

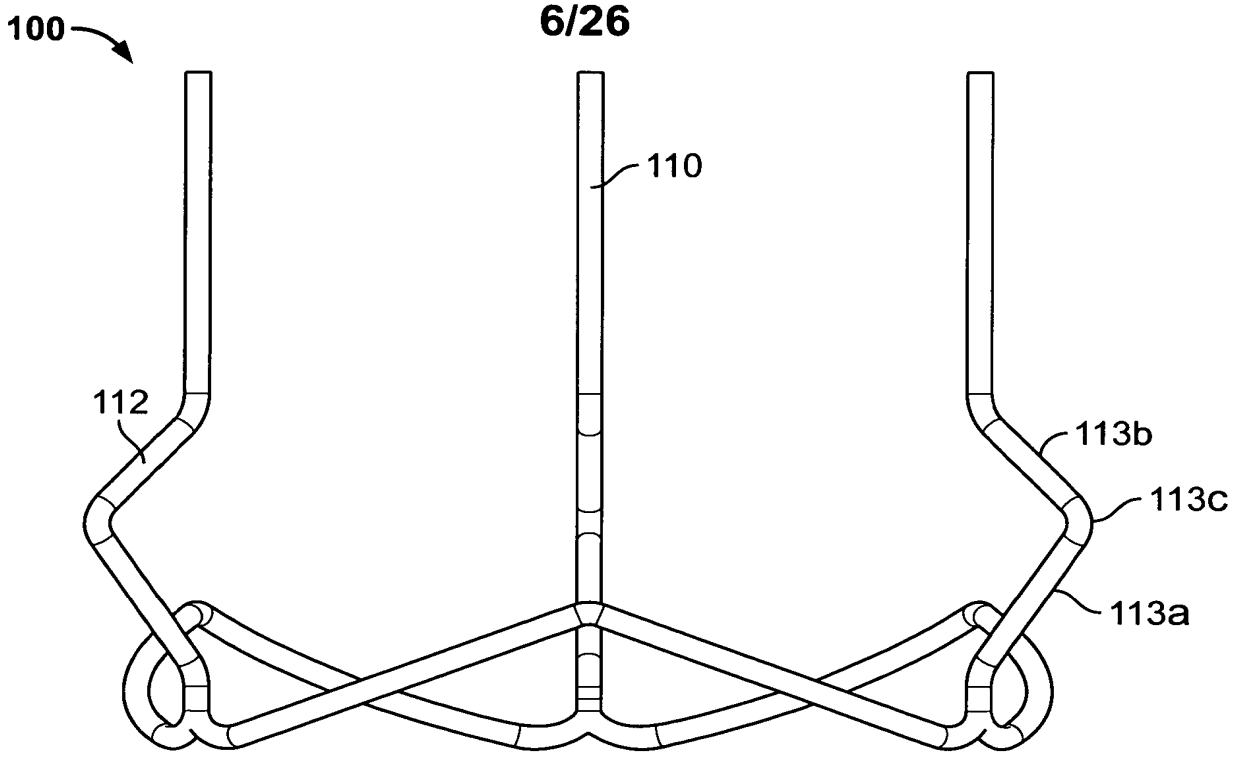

FIG. 4A

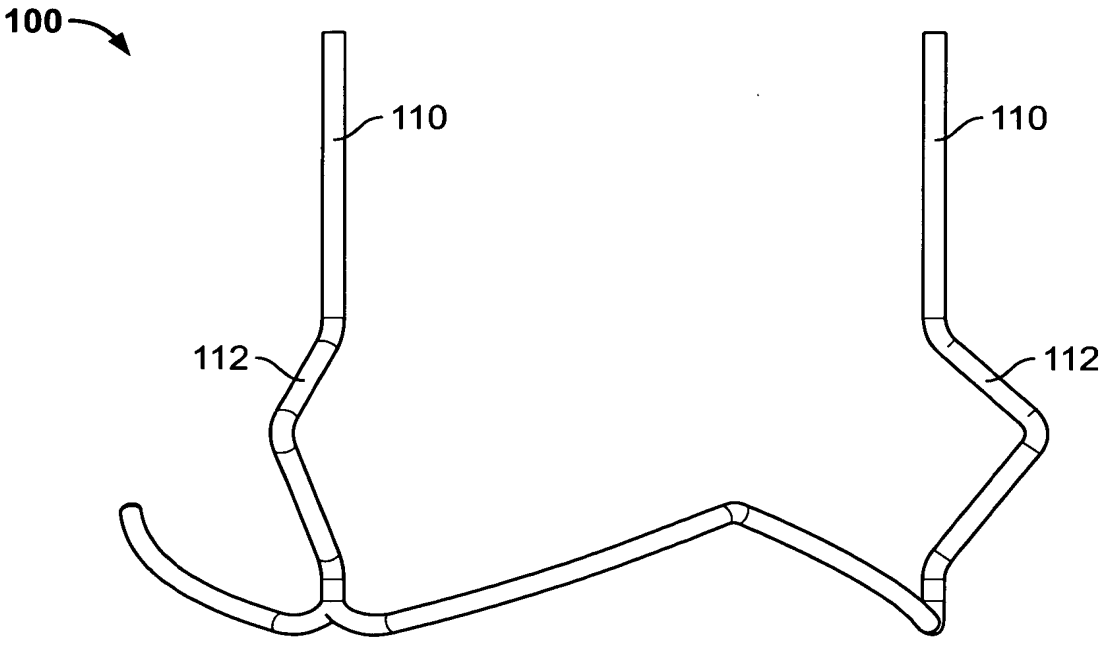

FIG. 4B

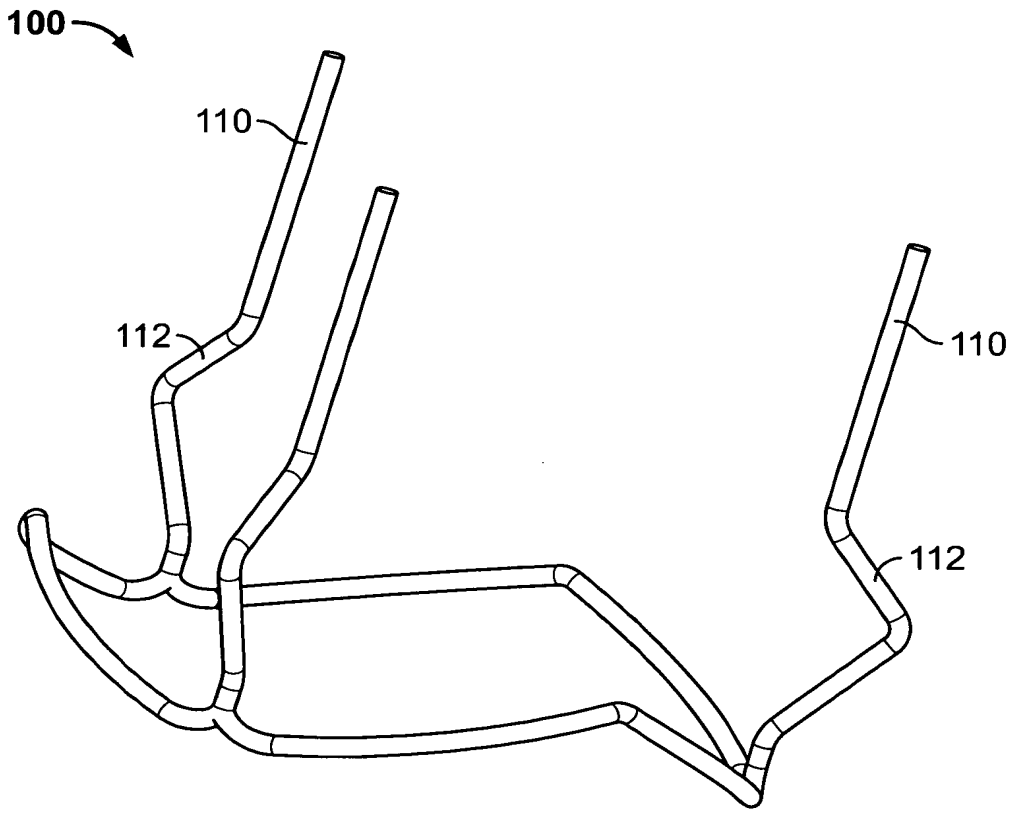

FIG. 4C

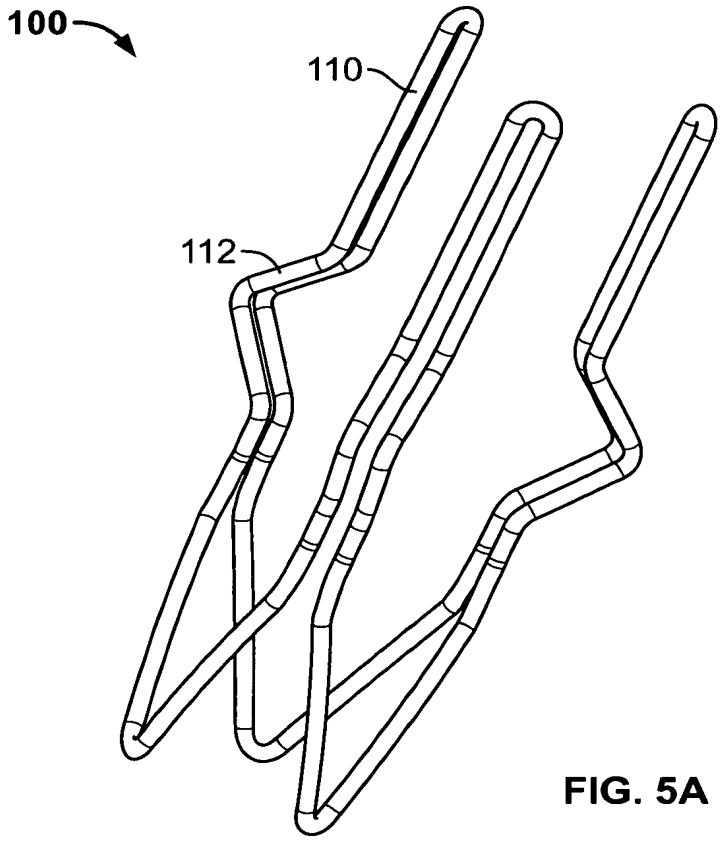

FIG. 5A

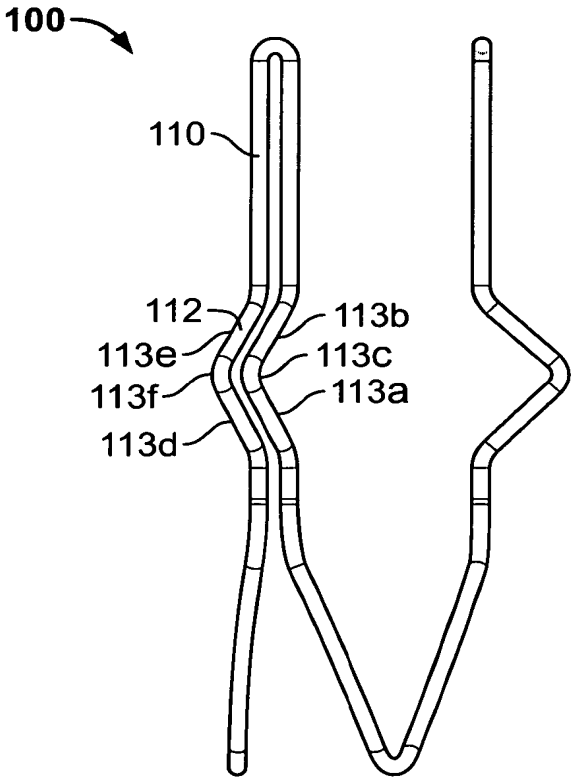

FIG. 5B

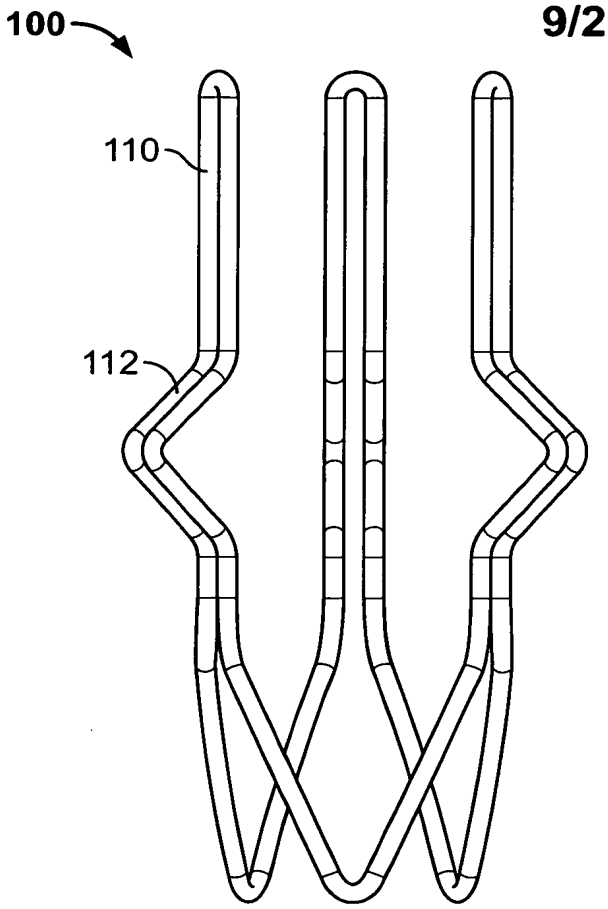

FIG. 5C

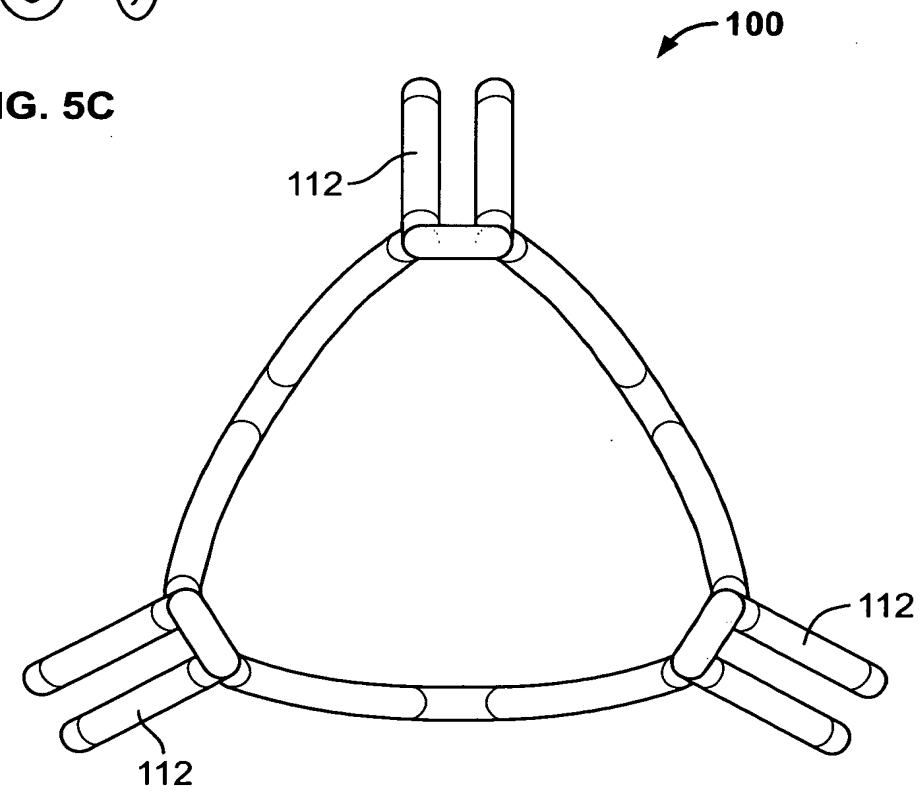

FIG. 5D

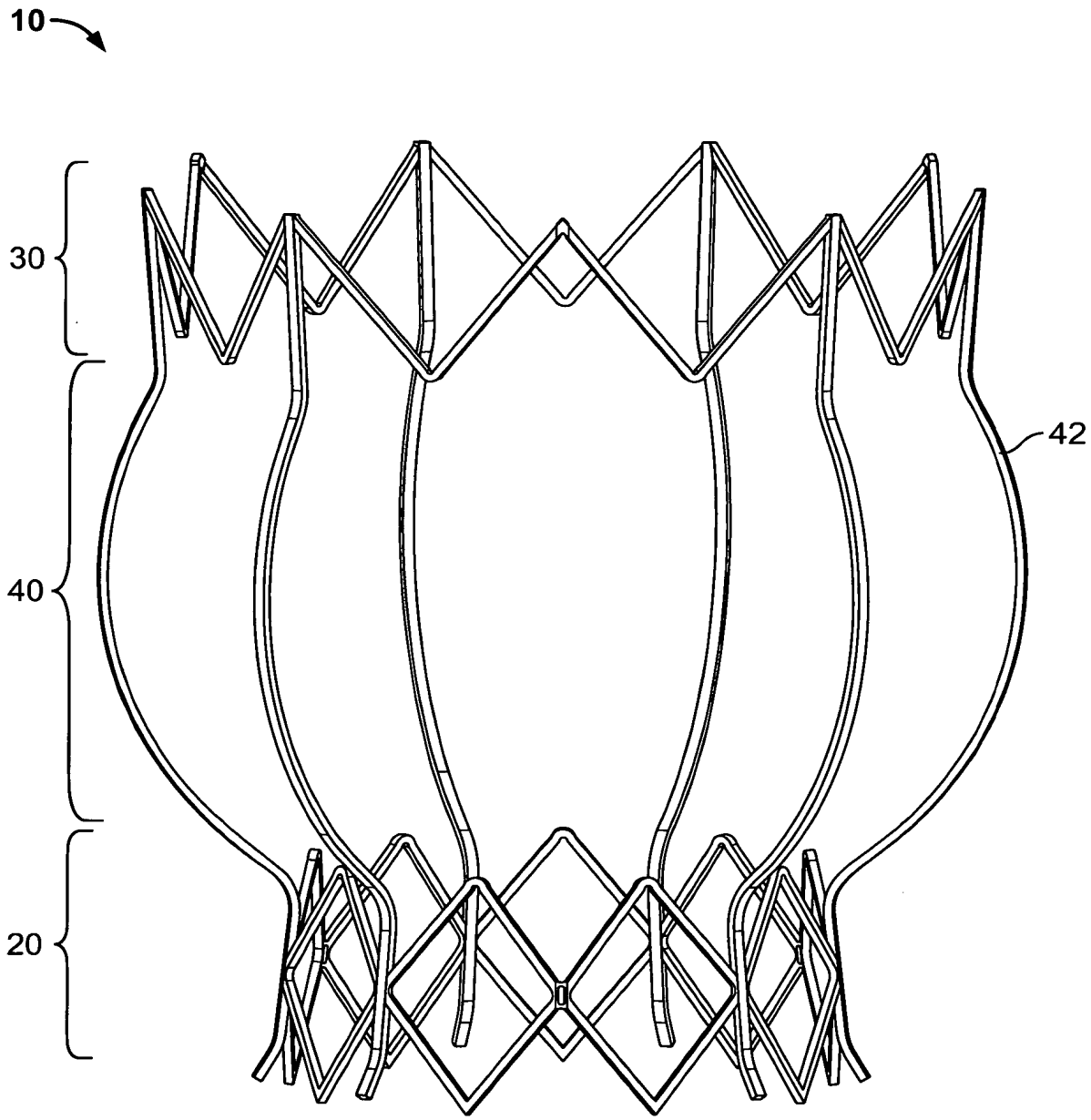

FIG. 6A

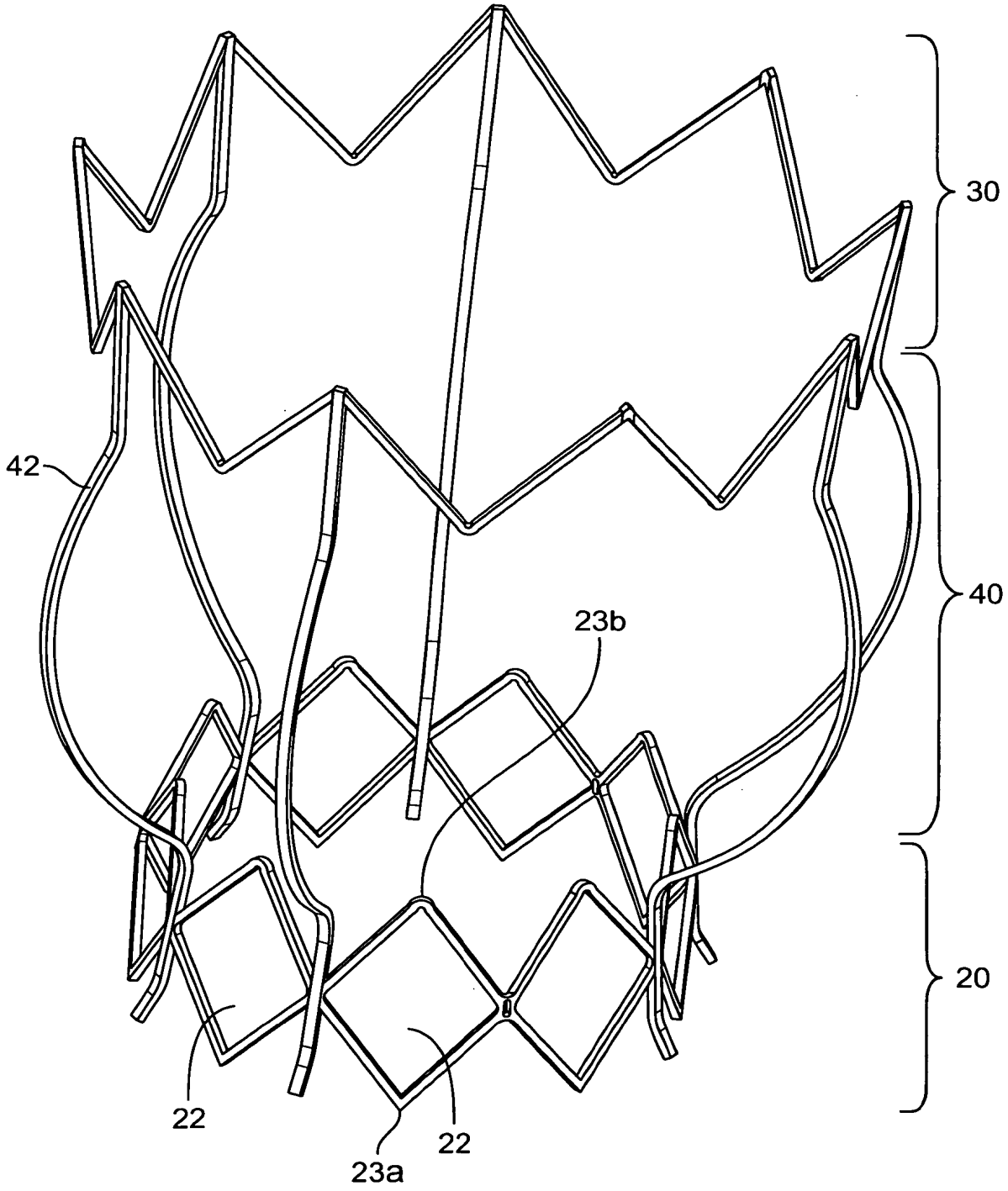

FIG. 6B

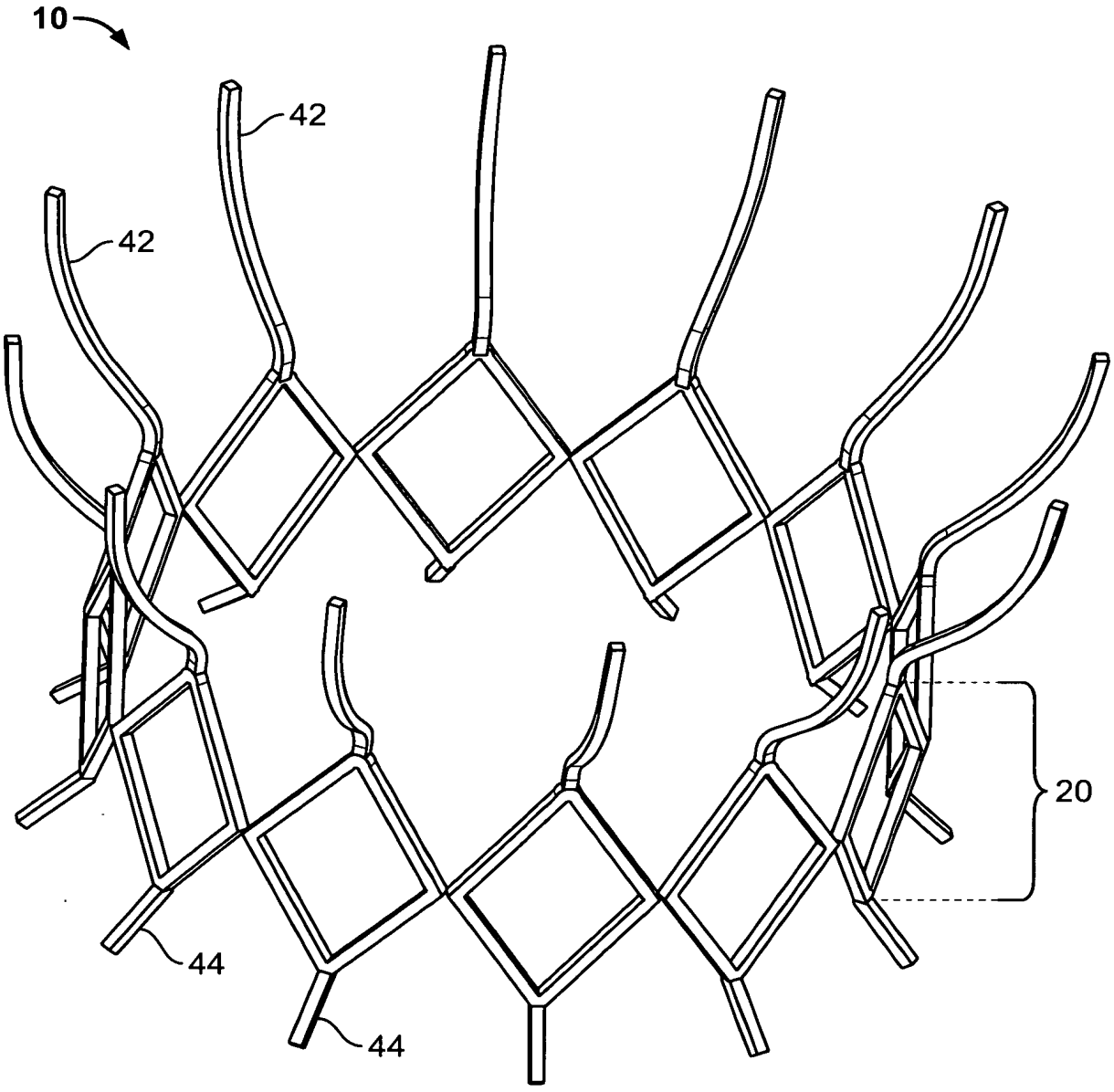

FIG. 7A

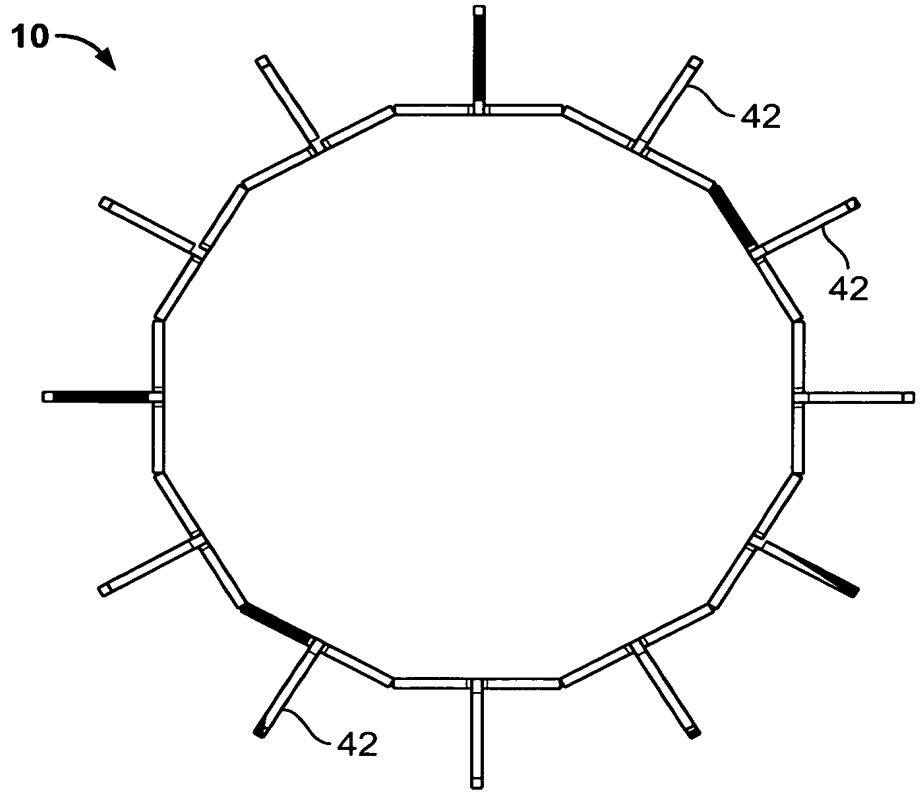

FIG. 7B

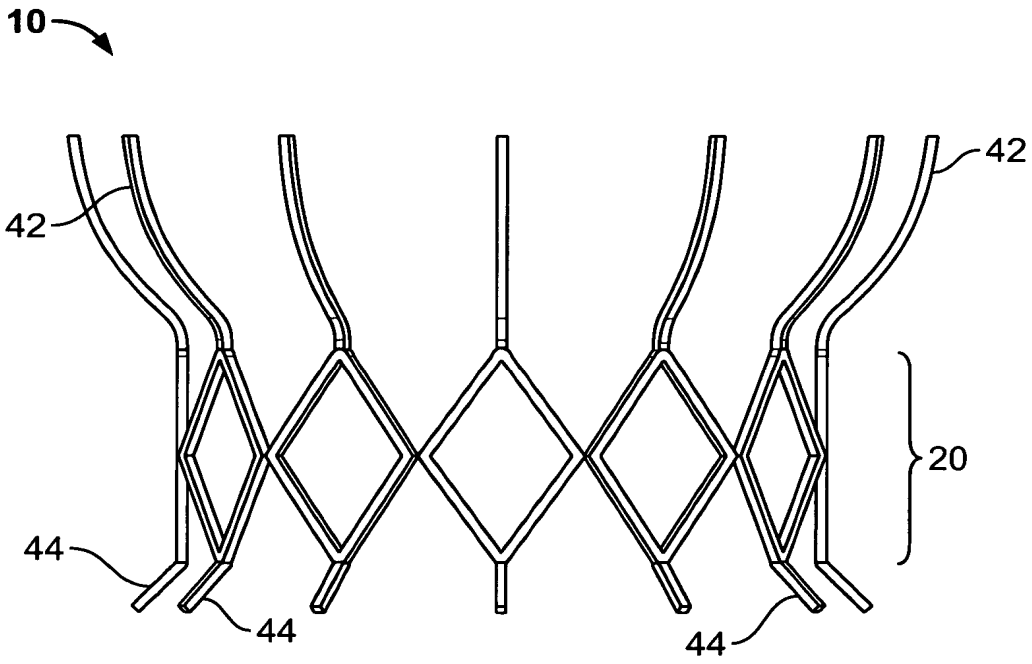

FIG. 7C

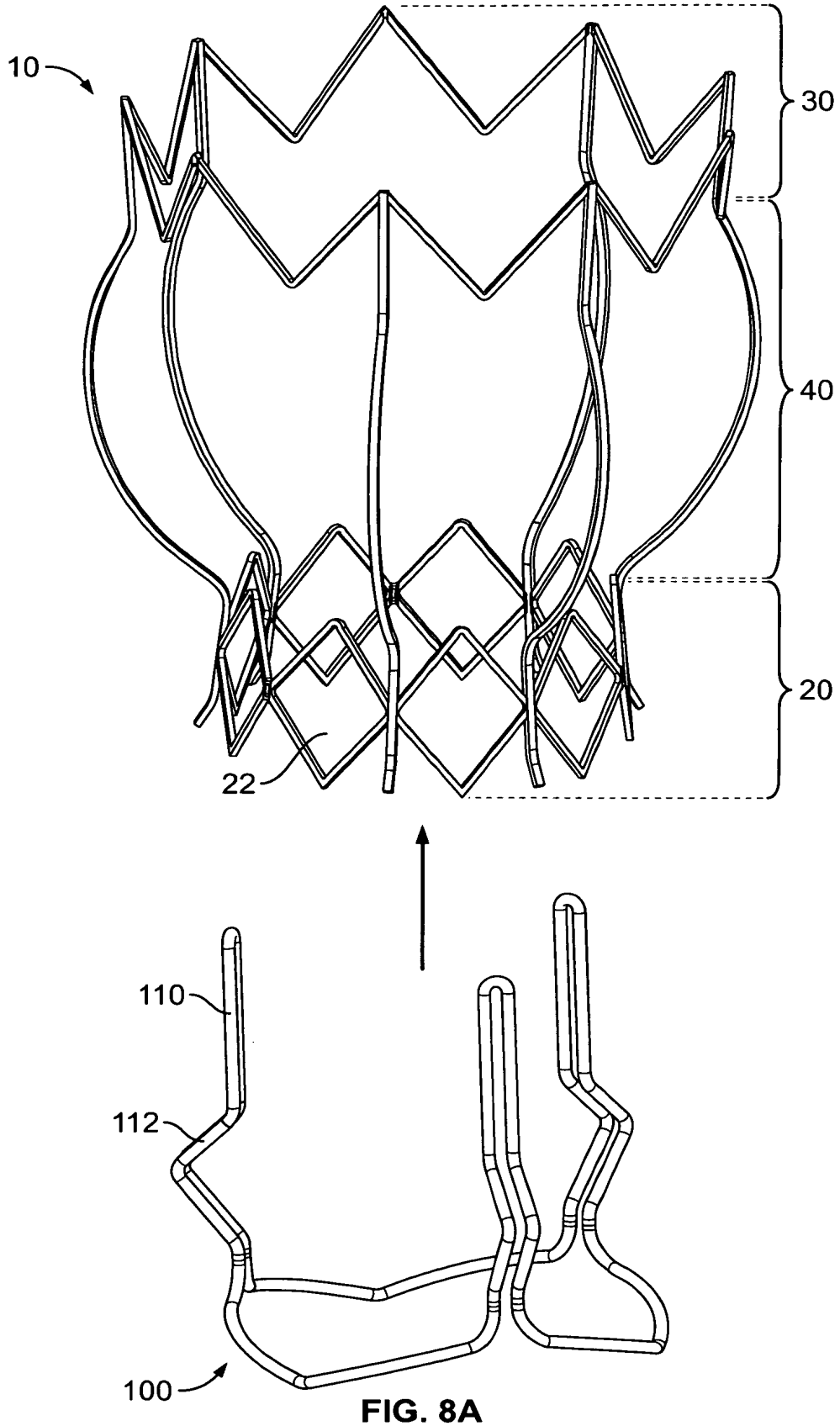

FIG. 8A

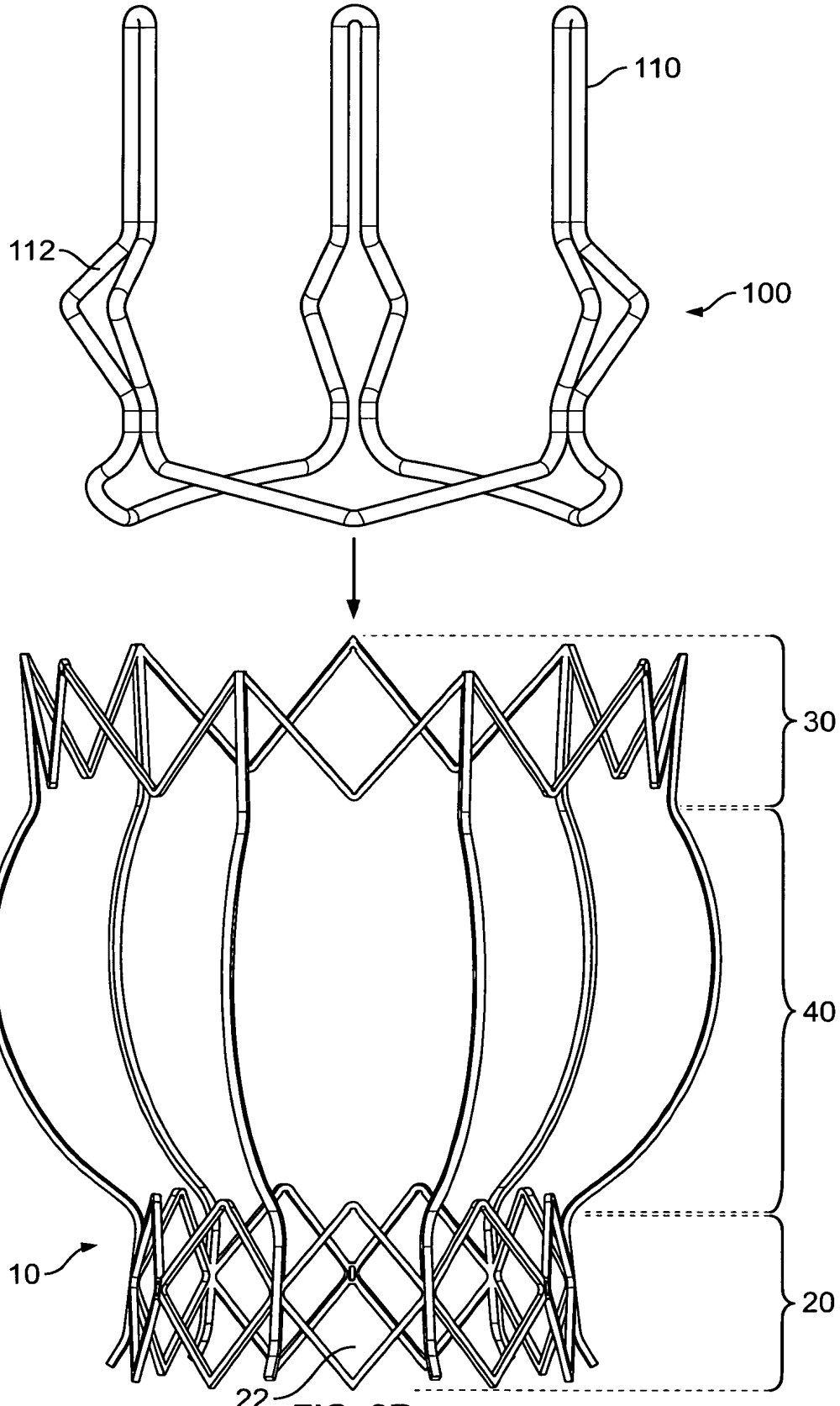

FIG. 8B

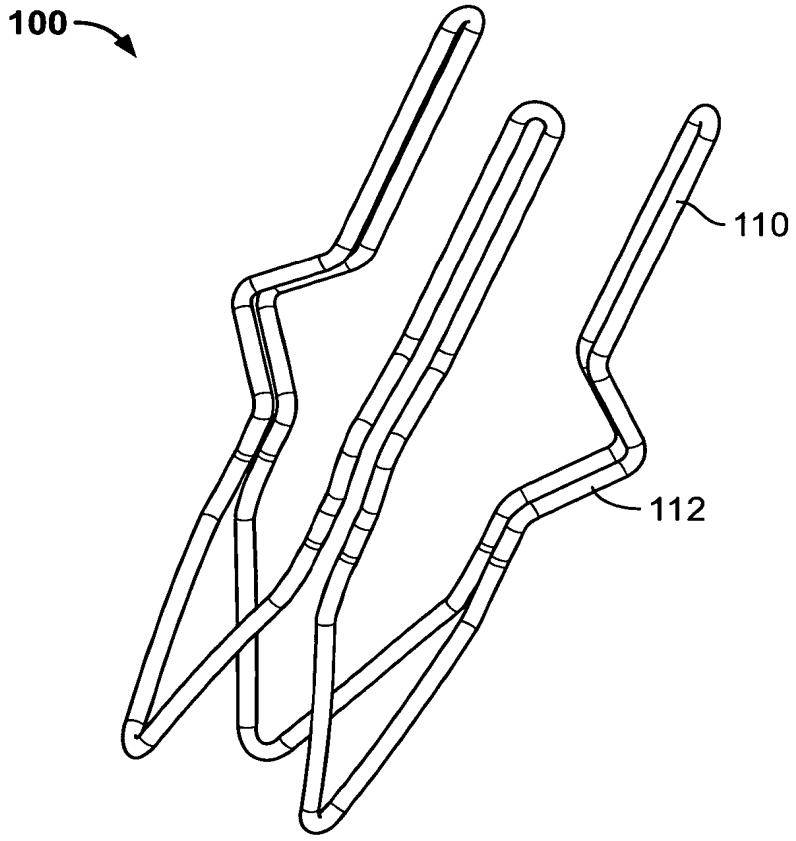

FIG. 9A

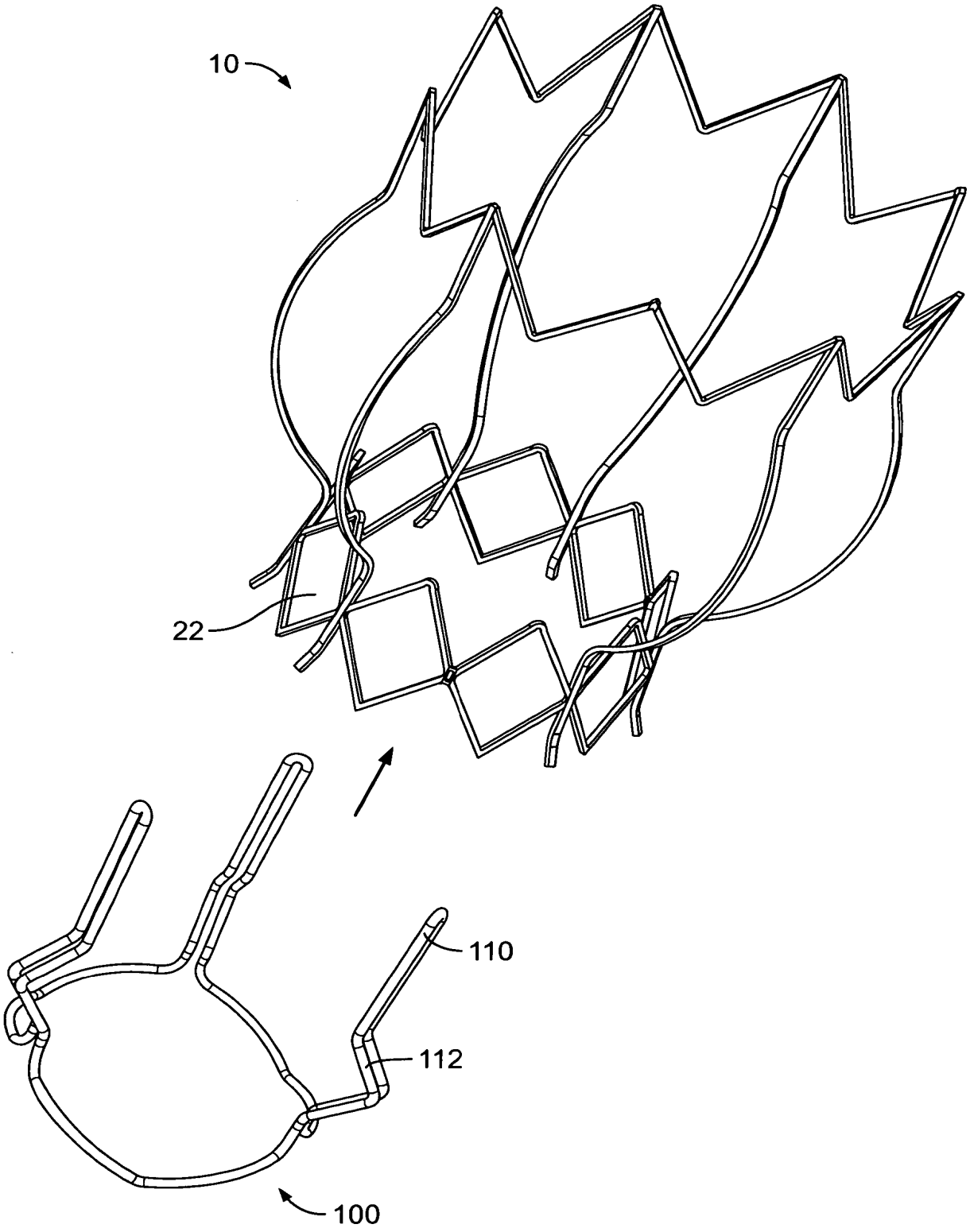

FIG. 9B

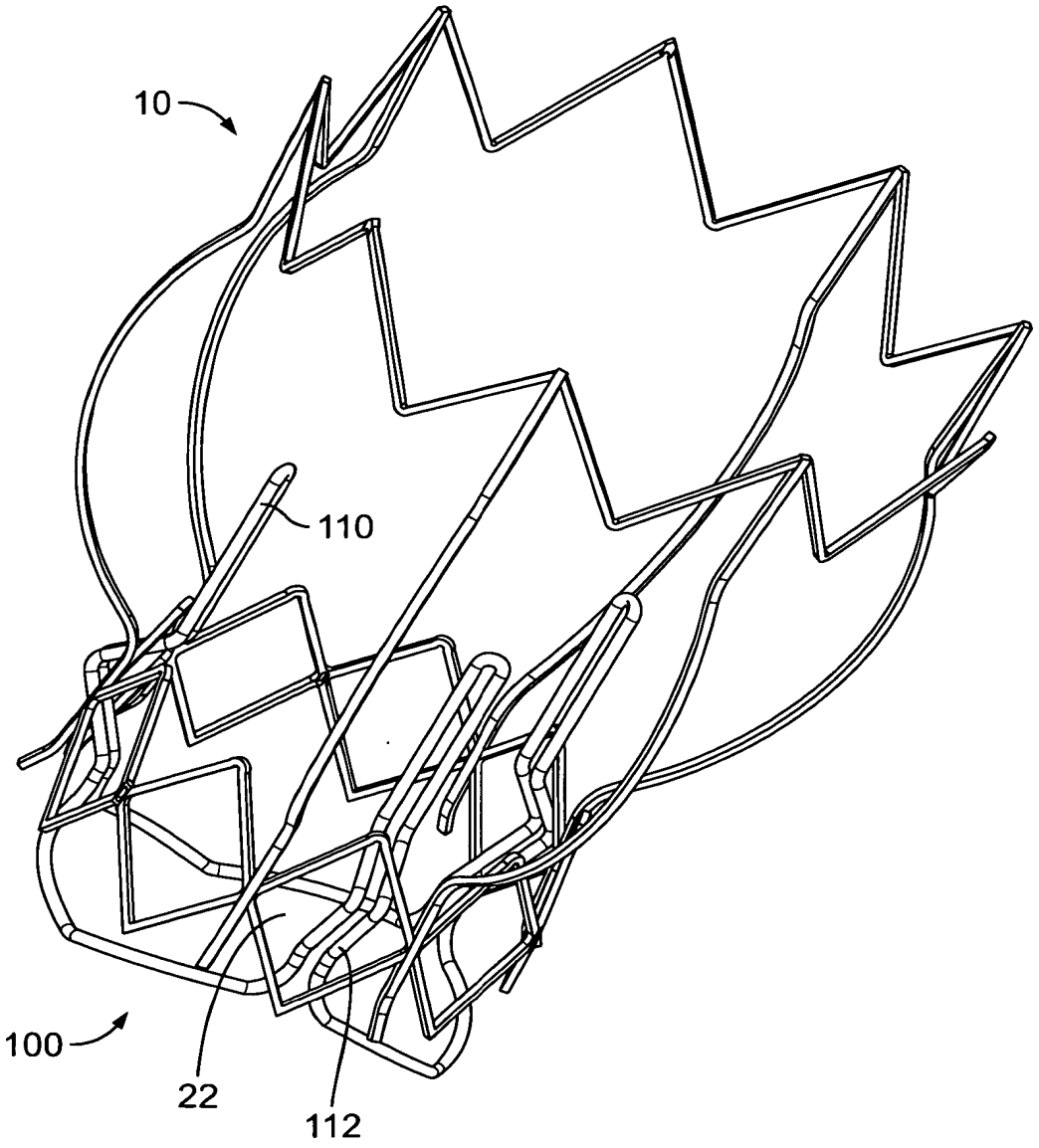

FIG. 9C

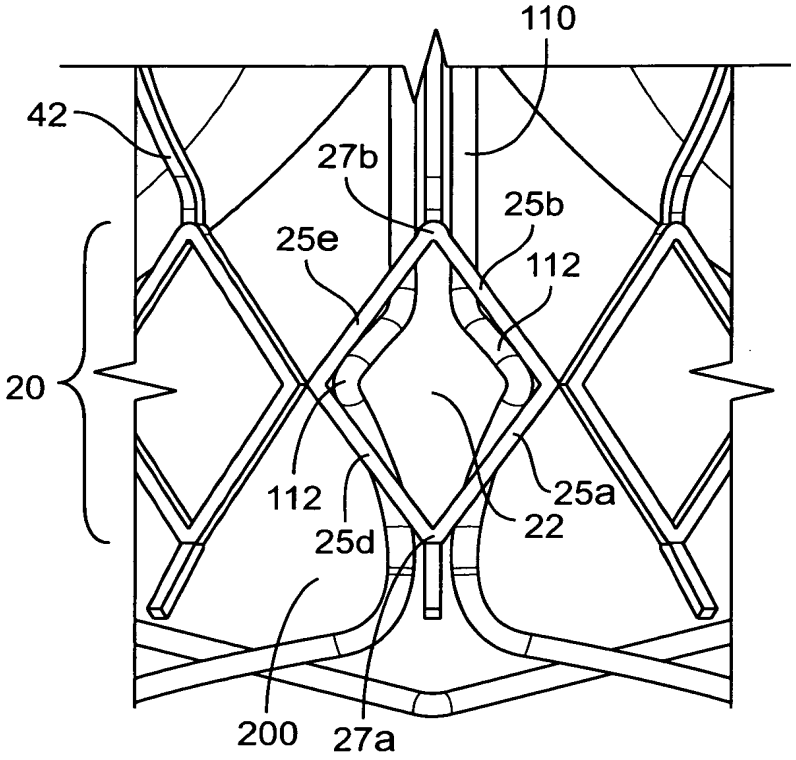

FIG. 10A

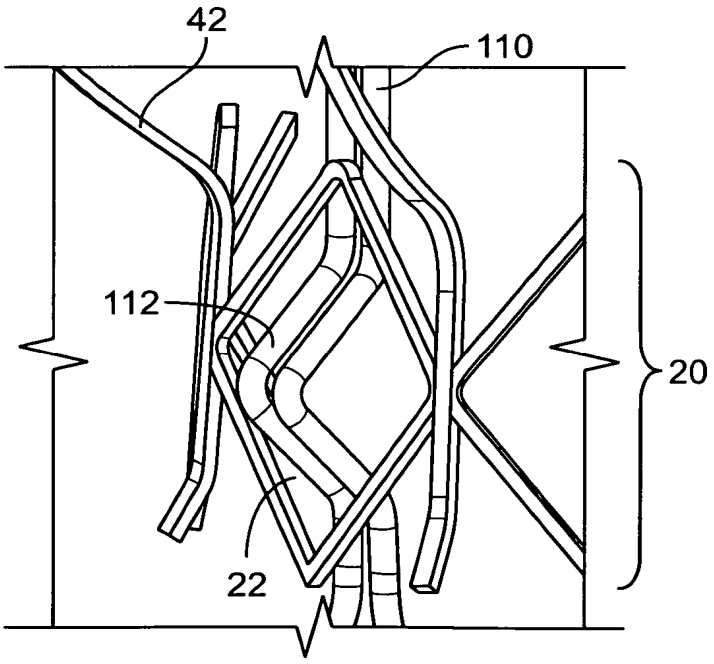

FIG. 10B

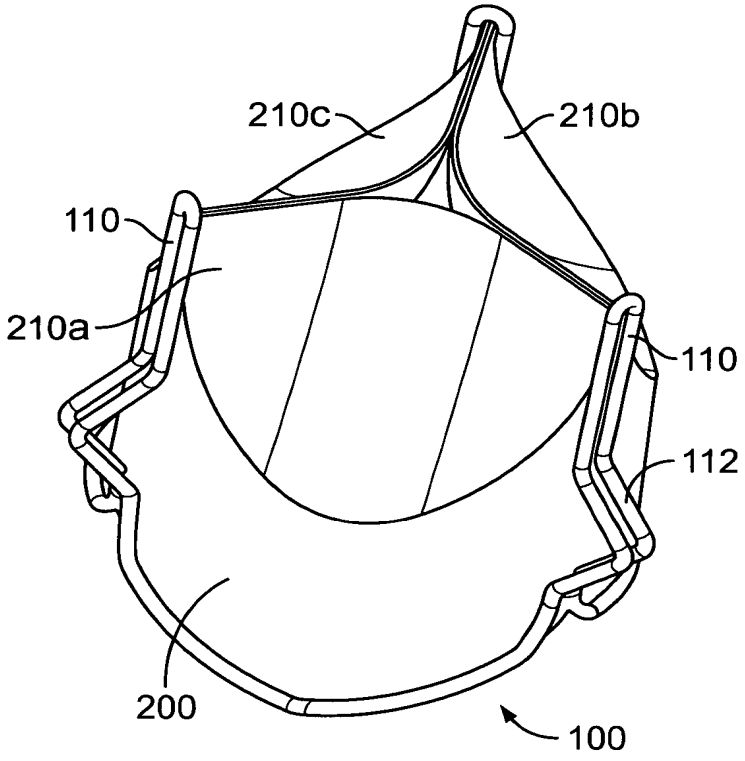

FIG. 11A

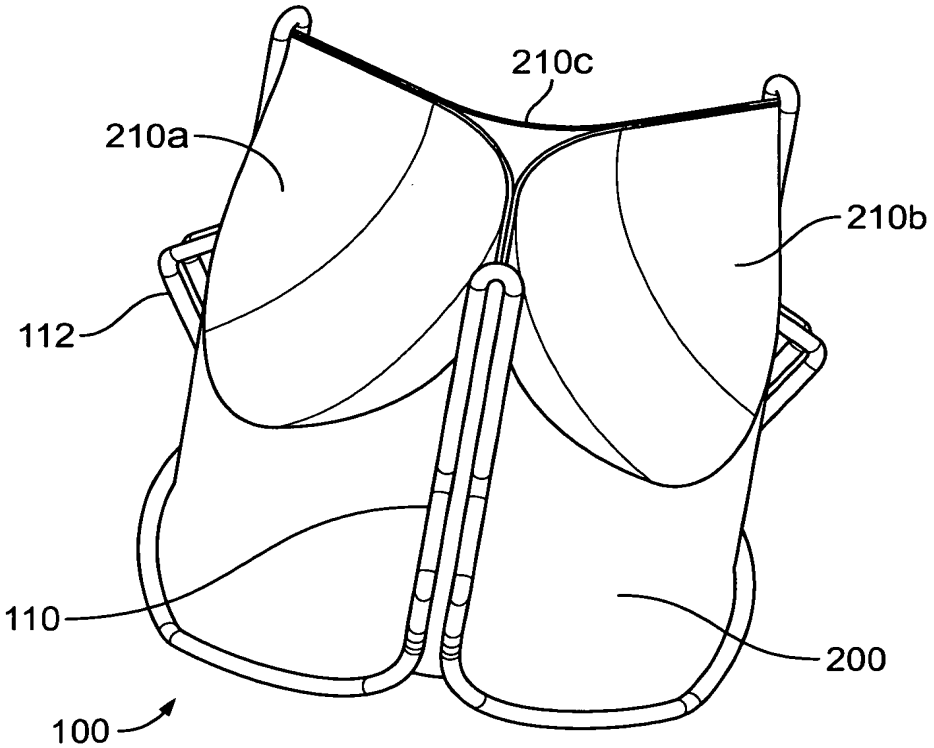

FIG. 11B

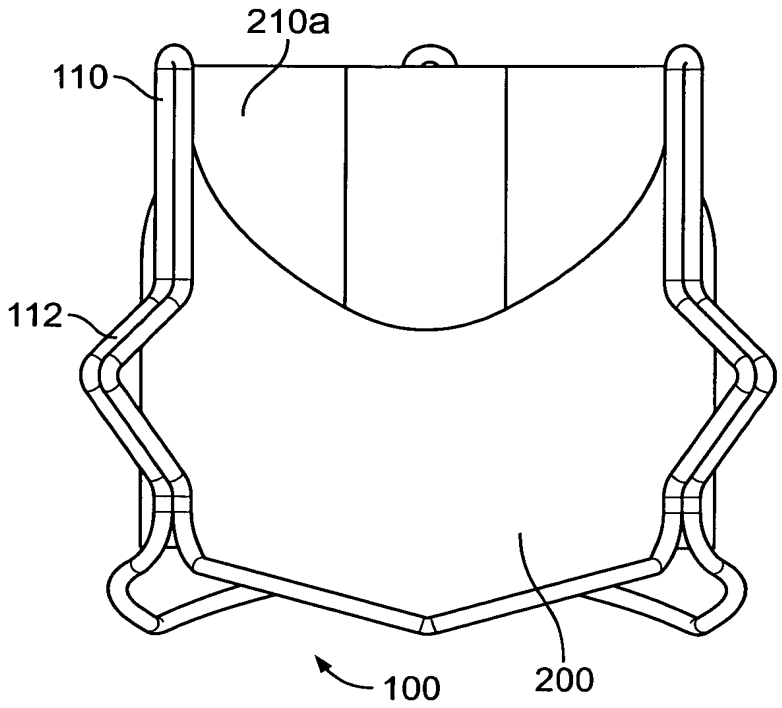

FIG. 11C

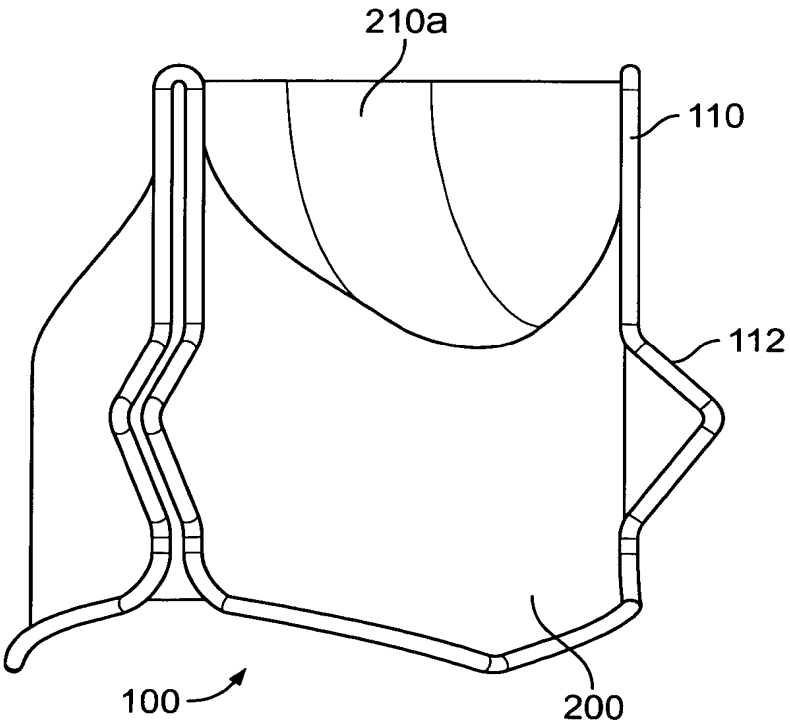

FIG. 11D

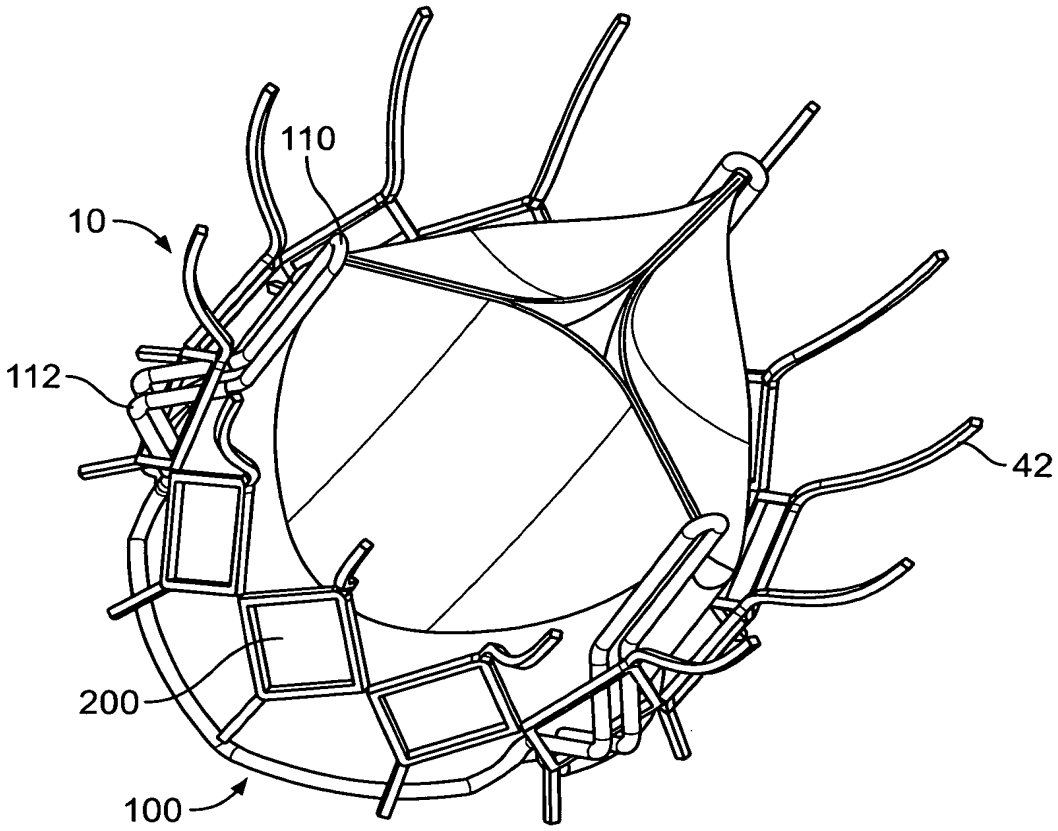

FIG. 12A

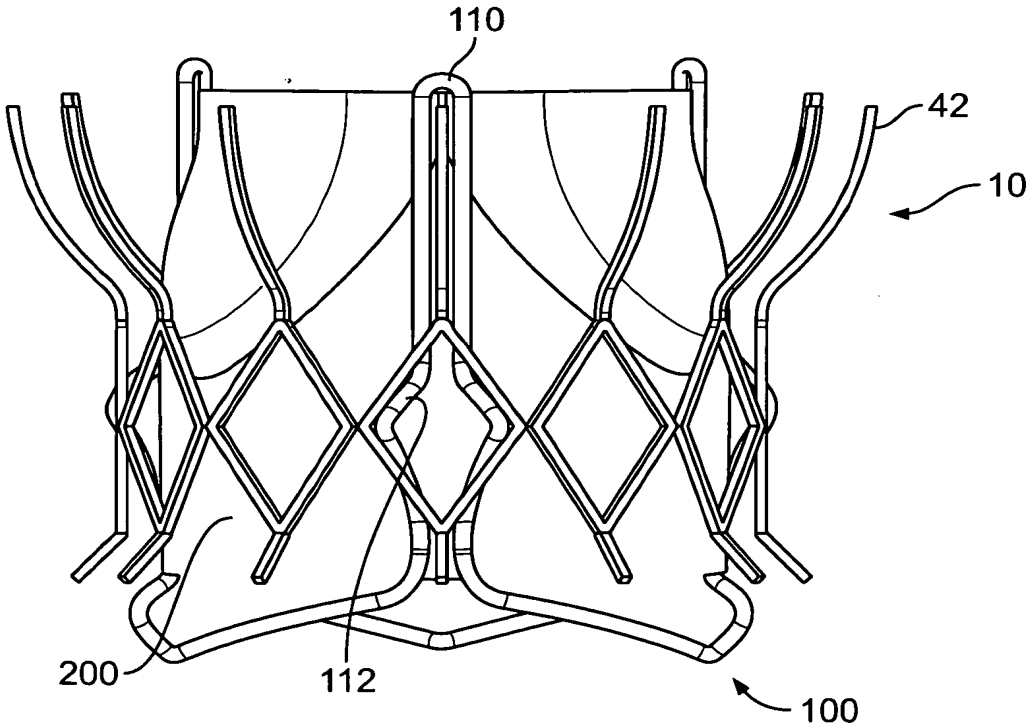

FIG. 12B

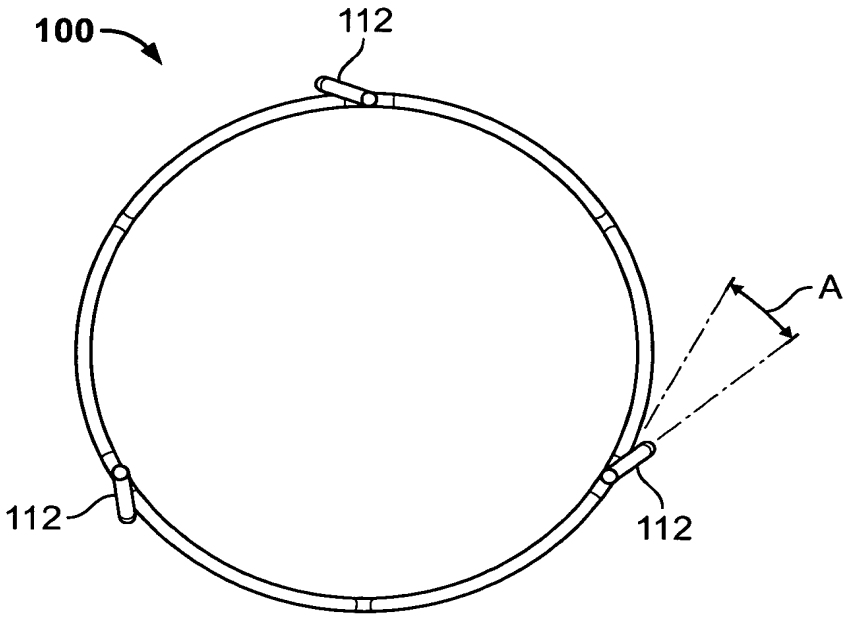

FIG. 13A

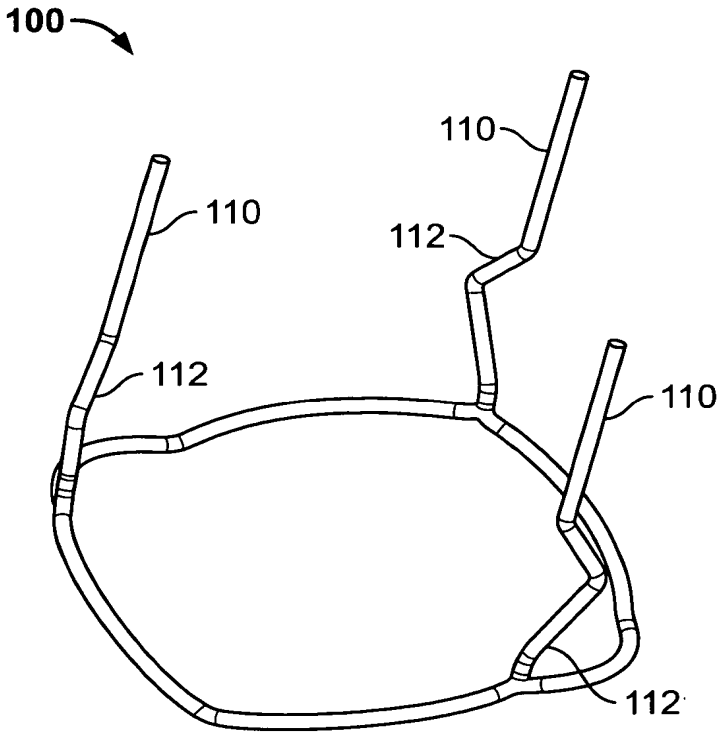

FIG. 13B

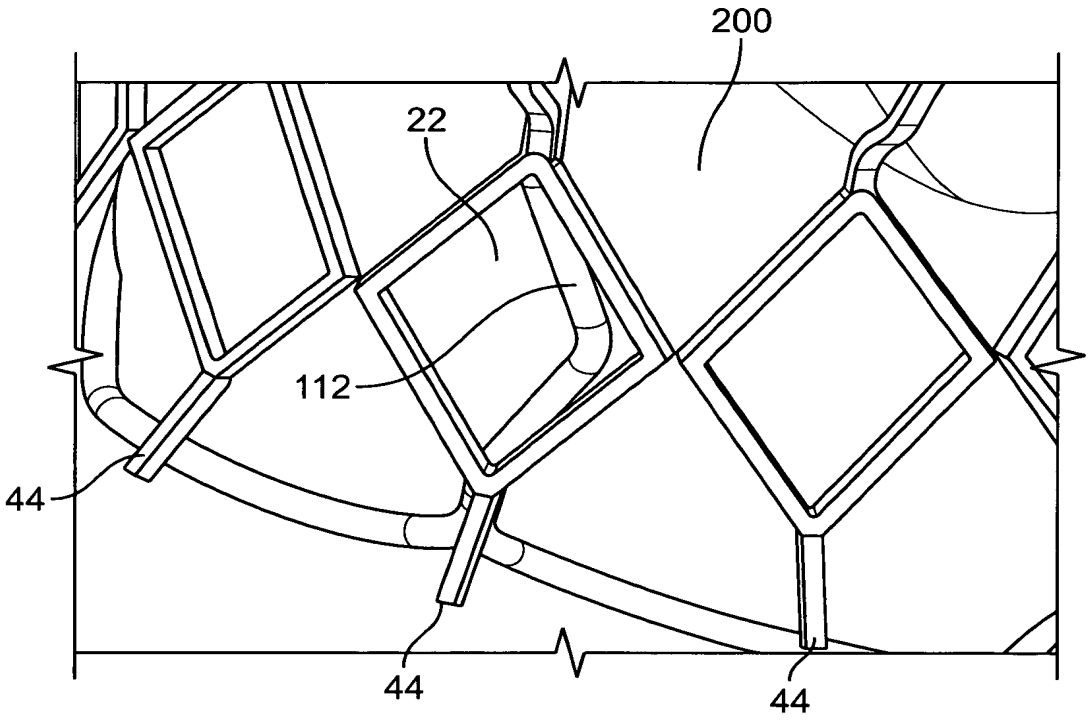

FIG. 13C

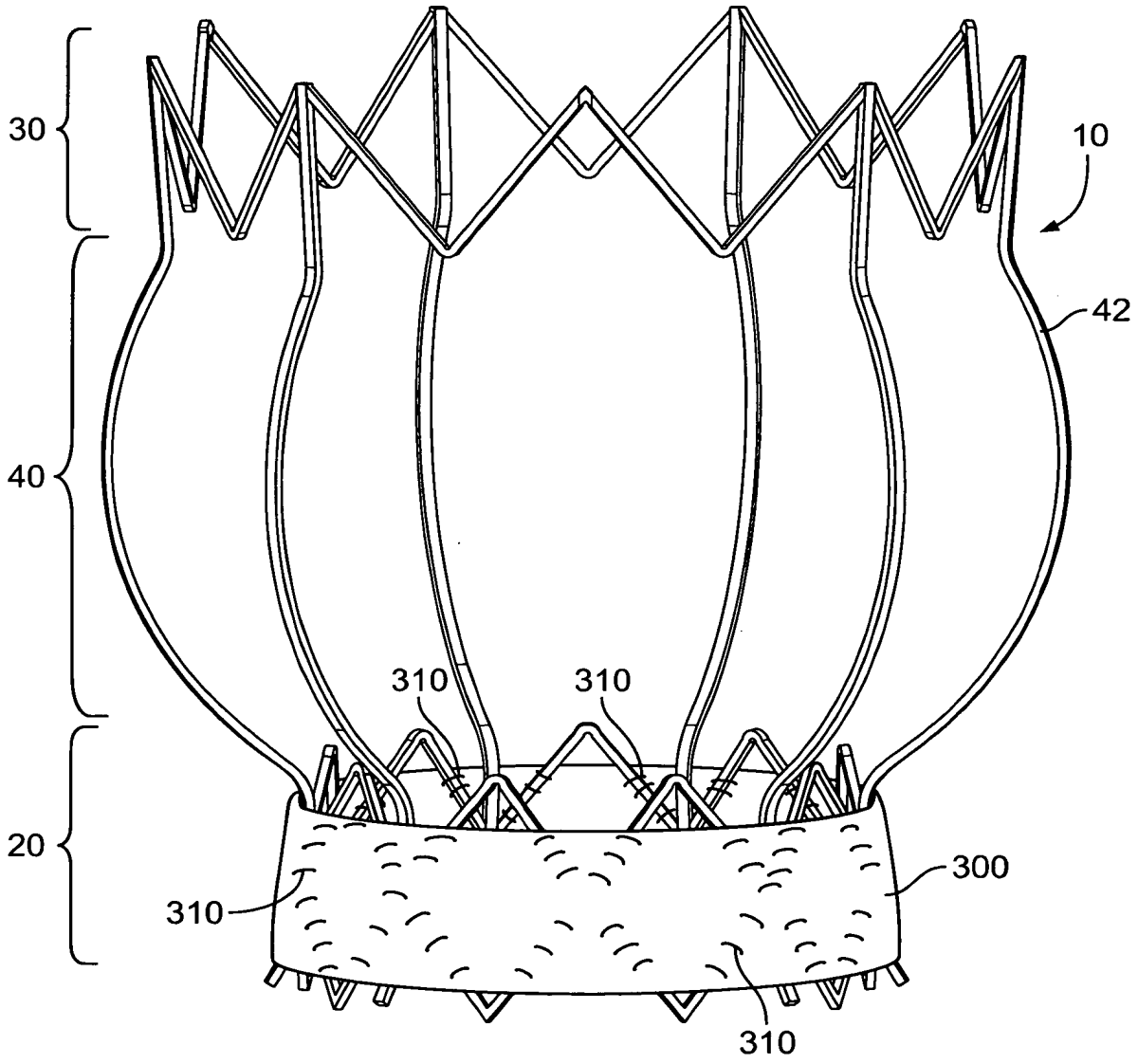

FIG. 14

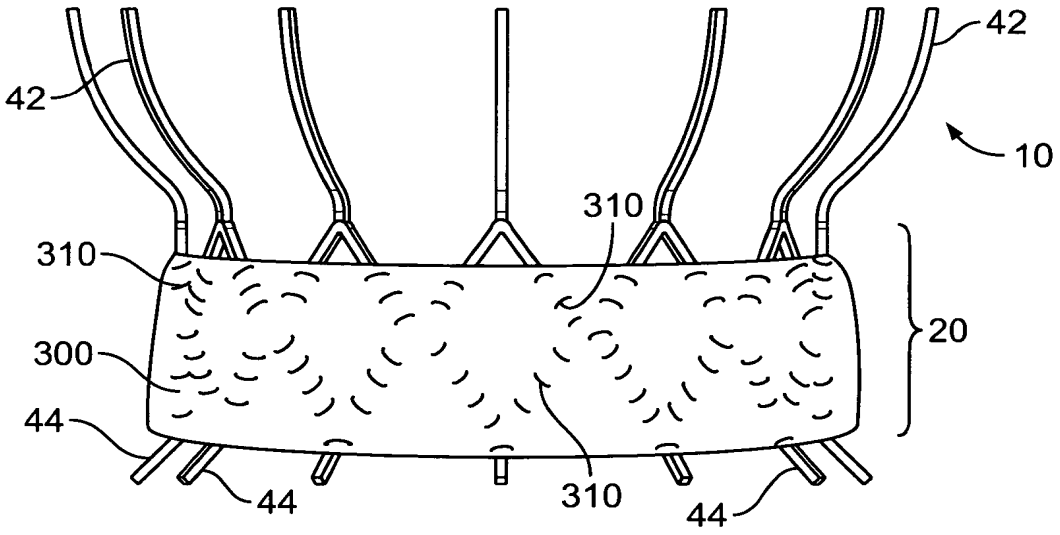

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/011177

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/127756 A (EDWARDS LIFESCIENCES CORPORATION) 30 November 2006 (2006-11-30) the whole document	1-4,11, 13-15, 17-19

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 February 2009	11/02/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Smith, Colin

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/011177

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-22
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/011177

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006127756 A	30-11-2006	CA 2607744 A1	30-11-2006
		CN 101180010 A	14-05-2008
		EP 1883375 A2	06-02-2008
		JP 2008541863 T	27-11-2008
		US 2006287719 A1	21-12-2006

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 April 2009 (23.04.2009)

PCT

(10) International Publication Number
WO 2009/052180 A1

(51) International Patent Classification:
A61K 8/67 (2006.01) *A61K 33/42* (2006.01)
A61Q 11/00 (2006.01) *A61P 1/02* (2006.01)
A61K 31/375 (2006.01)

(21) International Application Number:
PCT/US2008/079992

(22) International Filing Date: 15 October 2008 (15.10.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/874,637 18 October 2007 (18.10.2007) US

(71) Applicant *(for all designated States except US)*: **DENTECH, INC.** [US/US]; 17 Bellevue Avenue, Penndel, PA 19047 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **LEONHARDT, Charles, G.** [US/US]; 52 Cove Road, Huntingdon, NY 11743 (US). **BUSBY, John, C.** [US/US]; 17 Bellevue Avenue, Penndel, PA 19047 (US).

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(54) Title: ORAL HYGIENE PRODUCTS CONTAINING ASCORBIC ACID AND METHOD OF USING THE SAME

(57) Abstract: The present invention is directed to dental compositions, including dentifrices, containing ascorbic acid for removing and inhibiting dental biofilms which form plaque and tartar, and also for treating and preventing gingivitis and periodontitis. The ascorbic acid composition can contain many additional ingredients, including an enamel-strengthening component, and be used in many different forms, including breath spray, chewing gum, dental floss, dental powder, gargle, lozenge, mouth spray, mouth wash, tooth gel, tooth liquid, tooth paste and tooth strips. Also described is a method of using a dental composition containing ascorbic acid in order to treat plaque and tartar as well as gum disorders.

ORAL HYGIENE PRODUCTS CONTAINING ASCORBIC ACID AND METHOD OF USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

This PCT application claims priority from U.S. Patent Application Serial No. 11/874,637, filed on October 18, 2007, entitled Oral Hygiene Products Containing Ascorbic Acid and Method of Using the Same, which is a continuation-in-part application and, in turn, takes its priority from U.S. Patent Application No. 11/365,167, filed on March 1, 2006, also entitled Oral Hygiene Products Containing Ascorbic Acid and Method of Using the Same and all of whose disclosures are incorporated by reference herein.

BACKGROUND OF THE INVENTION

The present invention relates generally to compositions and methods useful in promoting oral health and hygiene and, in particular, to dental compositions comprising ascorbic acid for removing and inhibiting dental biofilm, plaque and tartar.

Bacteria are the primary etiologic agents in periodontal disease. Tooth decay and gum inflammation are often the result of microbial plaque activity, which includes bacterial products, leukocytes, epithelial cells and saliva components. In fact, more than 500 bacterial strains may be found in dental plaque. In the presence of saliva, proliferating bacteria attach to places with retained food such as the gum line, tongue, tooth spacing, pits and fissures. These bacteria have also evolved to survive in the environment of the tooth surface, gingival epithelium, and oral cavity. These bacteria decompose retained food, releasing toxic substances and forming plaque and tartar (an advanced form of plaque), together often referred to as dental calculus. This results in bad breath, tooth decay, gum inflammation and dental caries. Recent advances have led to the recognition that dental plaque is a biofilm and changes in thinking about the structure of dental plaque has led to an improved understanding of why periodontitis is so difficult to treat.

The majority of oral care products contain a large percentage of artificial ingredients which can be harmful when ingested. Some of the products induce allergic reactions and others are even carcinogenic when used in high dosages. Antibiotics have also been used to fight plaque formation. However, antibiotic applications usually result in the development of resistant microorganisms. As a consequence, there is a trend toward the use of safer ingredients in oral care products.

Oral care products containing safe ingredients, such as baking soda, are well known. However, high concentration of baking soda required to provide adequate cleaning is abrasive and distasteful. Saponin is another type of safe plaque cleanser, which produces foaming and cleans without the use of artificial surfactants. However, saponins are of plant origin (Quillaja and/or Yucca tree) and have to be extracted from plants, which is a laborious and time consuming process.

Ascorbic acid (vitamin C) is a safe ingredient and has been used in oral compositions. However, those compositions usually contain a small amount of ascorbic acid and mainly rely on other cleaning ingredients. For example, Japanese Patent 2005320321 A describes the use of a dentifrice composition comprising 0.01% to 15% ascorbic acid and hydroxyapatite; however, due to its low concentration of ascorbic acid, this composition only whitens teeth and does not treat and remove plaque and tartar from surfaces in the mouth. Other compositions use ascorbic acid but fail to efficiently utilize its strong and safe cleaning capacity heavily relying on catalysts for auto-oxidation, such as copper, and the synergetic action of other cleaning agents. None of the above prior art describes, suggests or renders obvious the enormous cleaning capacity of ascorbic acid crystals and/or granules unaided by other cleaning agents.

For the past several decades, the emphasis in oral hygiene has been placed on attempts to develop products and methods for removing plaque and tartar. To date, these attempts, and advances thereto, have experienced moderate success. There is, however, still a need for improved oral hygiene products and methods for inhibiting and removing dental calculus, especially tartar, and for preventing mouth disorders and disease.

More recently, advances in research technology have allowed researchers to study bacteria in their natural environment. These studies revealed that most bacteria live in complex communities called biofilms which adhere to surfaces in the mouth and are embedded in an extracellular slime layer. Once the bacterium attaches to a surface, it activates a whole different set of genes that gives the bacterium different characteristics from those that it had as a free-floating organism. It is now known that a biofilm community comprises bacterial microcolonies, an extracellular slime layer, fluid channels, and a primitive communication system. Dental bacterial plaque is a biofilm that adheres tenaciously to tooth surfaces, restorations, and prosthetic appliances as well as other surfaces in the mouth and throat regions of the body. Understanding the formation, composition, and characteristics of dental biofilm assists in its removal and control. Therefore, a need exists for an improved dental composition for removing dental biofilm in order to prevent the accumulation of plaque and tartar in the

mouth.

The present invention relates to a safe dental composition or dentifrice for treating dental biofilm, plaque and tartar. The invention also relates to the use of the dental composition for removing and inhibiting the formation of dental biofilm, plaque and tartar in a subject's mouth. The invention is highly efficient in plaque and tartar removal and inhibition and is also a natural tooth whitener and preservative.

BRIEF SUMMARY OF THE INVENTION

The invention is a dental composition comprising ascorbic acid as well as a method for using the composition in order to remove and inhibit dental biofilm, plaque and/or tartar in the mouth and throat regions of a body. There are several variations of the dental composition and the method of using same.

While the prior art avoids using high concentrations of ascorbic acid as harmful to tooth enamel, the present invention is a dental composition which contains a high weight concentration of ascorbic acid in order to effectively remove dental calculus from the mouth and throat regions of a body. The dental composition can contain additional ingredients including an enamel-strengthening component (*e.g.*, hydroxyapatite) which will effectively and efficiently protect tooth enamel. If desired, additional ingredients can also be added to the composition of the invention including sweeteners, flavoring and coloring agents to name only a few. Also, the composition of the invention can be used in a variety of commercial products such as toothpaste, chewing gum, mouthwash and mouth spray, to name only a few, in order to cover a wide range of consumer needs.

The method of the present invention is directed to the use of a dental composition comprising ascorbic acid such that the composition is taken into the mouth for a sufficient period of time to begin to attack and/or remove dental biofilm, plaque and/or tartar and strengthen enamel on teeth after which the composition is expectorated from the mouth. The method also has the added advantage of removing dental biofilm from other surfaces of the mouth and throat regions, including the larynx and vocal cords.

It is an object of the present invention to provide an improved dental composition for removing biofilm, plaque and/or tartar from a user's mouth and throat regions of the body. It is also an object of the present invention to provide a method for removing, controlling and/or inhibiting biofilm, plaque and/or tartar in a user's mouth. It is another object of the present invention to provide a safe oral hygiene composition which promotes human and animal health.

To this end, it is yet another object of the present invention to prevent mouth and gum disorders such as caries, gingivitis, and other periodontal diseases. Still another object of the present invention is to provide a safe, healthy and efficient cleaning procedure for especially children by eliminating the need for long and extensive brushing. Yet another object of the invention is to provide an improved dental composition and method of using same which is convenient, portable and ingestible.

DETAILED DESCRIPTION OF THE INVENTION

The invention is based on the enormous cleaning capacity of ascorbic acid crystals, granules and/or any other form of ascorbic acid unaided by any other cleaning ingredients. Preferably, ascorbic acid is in a crystalline form. The use of the dental composition is not limited to humans but can be effective in many other subjects, including animals that experience the formation of dental biofilm, plaque and/or tartar in their mouth and throat areas. More specifically, the present invention is directed to a dental composition for removing and inhibiting at least one of dental biofilm, plaque and tartar comprising an effective amount of ascorbic acid. The composition is also effective in treating and/or preventing teeth and gum disorders.

Ascorbic acid is a non-toxic compound which is harmless when ingested. The molecular structure of ascorbic acid is Vitamin C which is required for the growth and repair of tissues in all parts of your body. It is necessary to form collagen, an important protein used to make skin, scar tissue, tendons, ligaments, and blood vessels. Vitamin C is also essential for the healing of wounds, and for the repair and maintenance of cartilage, bones, and teeth.

Vitamin C deficiency can lead to dry and splitting hair; gingivitis (inflammation of the gums) and bleeding gums as well as rough, dry, scaly skin; decreased wound-healing rate, easy bruising; nosebleeds; weakened enamel of the teeth; swollen and painful joints; anemia; decreased ability to ward off infection; and, possibly, weight gain because of slowed metabolic rate and energy expenditure. A severe form of vitamin C deficiency is known as scurvy, which mainly affects older, malnourished adults. The body does not manufacture vitamin C on its own, nor does it store it. It is therefore important to include plenty of vitamin C-containing foods in a daily diet. Thus, ascorbic acid is not only harmless but also important for healthy functioning. Most preferably, the present invention uses high concentrations of ascorbic acid in combination with an enamel-strengthening component to clean teeth and protect tooth enamel.

Dental plaque is a biofilm which simply stated is a fatty substance consisting of

bacterial colonies surrounded by a gel-like intercellular substance derived chiefly from the bacteria themselves. Plaque also contains saliva, epithelial cells and leukocytes. It usually accumulates on the surface of teeth, gums, gum lines, on the tongue and in the throat region resulting in bad breath, tooth decay, gum disorders and caries. Bacterial colonies of the plaque use dietary carbohydrates as a source of energy producing acids. The acids demineralize tooth enamel and dentine attacking gum tissue and reacting with the calcium in the teeth. Different studies have confirmed the role of microbial plaque as a major factor in dental caries and periodontal diseases.

The most common types of periodontal disease are gingivitis and periodontitis. Gingivitis is an early stage gum disease characterized by gum inflammation, swelling and bleeding. Periodontitis is a late stage gum disease, in which tooth supporting bone is slowly lost and, if left untreated, can result in tooth loss. In view of dental biofilm and plaque's major role in dental diseases, one of the objects of the present invention is to provide safe and effective oral hygiene composition for combating bacteria associated with dental plaque, caries, and periodontal diseases. In one embodiment of the present invention, the dental composition of the invention breaks down the dental biofilm barrier formed, for example, on the surface of a tooth so that antibacterial agents in the composition can attack bacterial colonies that create plaque and, eventually, tartar. Accordingly, the present invention provides an improved dental composition for relatively fast and efficient removal and inhibition of dental biofilm and plaque thereby preventing and treating periodontal disease, including gingivitis and periodontitis.

The present invention also efficiently attacks, removes and inhibits tartar. Tarter is generally considered to be an advanced form of plaque which forms by a complex biological process. Very simply, tartar is formed when inorganic salts and phosphates in saliva deposit on plaque, calcify and form a hard, strong surface. Relative to plaque, tarter is difficult to remove once formed and thus is usually removed by mechanical means such as ultrasonic scrapers, picks and brushes. Tartar that remains on teeth for a long time period of time may result in serious tooth and gum disorders. While the dental composition of the present invention has some abrasive features, the ascorbic acid effectively breaks down tarter by primarily a chemical means. As a result, each application of the dental composition of the invention reduces and inhibits tartar formation thereby resulting in the prevention of dental caries and periodontal diseases.

The dental composition of the present invention and, in particular, a relatively high concentration of ascorbic acid, attacks dental biofilm which leads to the formation of dental

calculus in the mouth and throat areas of a subject. It is believed that dental biofilm differs from subject to subject depending on body chemistry including, among other things, the pH of saliva. Typically, the solubility of plaque is about pH 5.5. As a result, it is preferred that an aqueous solution containing the dental composition of the present invention has a pH of about 4.5 to about 5.5. This can be accomplished, for example, by combining a sufficient quantity of the dental composition with saliva in a mouth so that a pH of less than about 5.5 is achieved in the mouth and throat regions as this will begin to solubilize plaque in these regions of the body. Thus, preferably, the pH of the dental composition of the present invention is less than about 5.5.

Ascorbic acid crystals and/or granules in the form of dental powder can be viewed as the most efficient embodiment of the invention. Preferably, the dental composition of the present invention comprises from about 15% to about 100% ascorbic acid, most preferably the dental composition comprises greater than 50% ascorbic acid by weight. The present invention can also be used in other forms, including a liquid form as an aqueous and/or alcohol solution. However, forms other than dental powder are expected to contain a lower concentration of ascorbic acid as the concentration will be limited by the amount of ascorbic acid that will enter a solution. For example, it is expected that an aqueous solution of the dental composition will contain a maximum of about 45% ascorbic acid.

Also, in addition to a dental powder, the dental composition of the present invention can be a breath spray, chewing gum, gargle, lozenge, mouth spray, mouth wash, tooth gel, tooth liquid, and toothpaste. The toothpaste form can be a water-free paste such as a water-free glycerol paste and aqueous forms of the dental composition can be made with or without alcohol. The aqueous solutions can contain up to about 80% water and the alcohol solutions can contain up to about 30% denatured alcohol and up to about 50% water. The alcohol used can be, but is not limited to, thymol and menthol.

In other embodiments of the present invention the dental composition is impregnated in a dental tool. Such dental tools include, but are not limited to, a toothbrush, tooth strips, dental floss, and dental instruments. These tools function such that, when used in a mouth, the dental composition contacts saliva, goes into solution, and begins to attack dental biofilm, plaque and tartar.

The toothpaste, dental powder and mouthwash forms of the invention are more suitable for use in domestic or household settings, where they are applied to teeth with or without a brush. For example, after toothpaste application and brushing of a subject's teeth and mouth

regions are completed, the mouth can be easily rinsed with water and the water and toothpaste expectorated from the mouth. Similarly, the mouthwash form of the present invention can be comfortably used in a domestic or household setting where a person has an opportunity to extensively rinse his or her oral cavity. After the rinse is completed, the mouthwash form of the present invention is expectorated and, if desired, the oral cavity is further rinsed with, for example, water. Importantly, any accidental swallowing will not be harmful considering that the dental composition is ingestible.

In contrast to the toothpaste, dental powder and mouthwash, which are more suitable for domestic use, the mouth spray and chewing gum forms of the invention can be universally used. Although many people are willing to take oral hygiene measures throughout the day, they often find those measures to be inconvenient, and sometimes awkward. For example, they may not have constant access to a bathroom or a sink and, therefore, are unable to use toothpaste or mouthwash. Also, they may be uncomfortable being seen carrying around items such as a toothbrush, toothpaste or a bottle of mouthwash. Consequently, there is a great need for oral hygiene products, like the mouth spray and gum forms of the present invention, which are convenient, portable and ingestible.

The mouth spray of the present invention merely requires spraying a solution of the dental composition into a person's mouth and retaining it in the mouth for an appropriate amount of time such that the composition begins to remove dental biofilm, plaque and/or tartar. Typically, the dental composition needs to remain in the mouth for less than about 2 minutes in order to ensure its effectiveness. After that time period has passed, the dental composition can be safely swallowed or simply expectorated from the mouth. It is envisioned that mouth sprays of the present invention will be packaged in portable bottles in order to fit into pockets, purses and bags.

The chewing gum form of the present invention is another effective form of the present invention. Plaque and even tarter can be dislodged or otherwise removed from mouth surfaces by chewing the gum for sufficient period of time. Furthermore, a person can continue chewing the gum even after plaque is dislodged or removed in order to inhibit plaque accumulation and tarter formation over longer time periods.

Preferably, the size of the ascorbic acid particles is greater than about 5 microns. Most preferably, the particle size is about 5 microns to about 100 microns. When used in high concentrations (ranging from about 15% to about 100% by weight), the ascorbic acid particles have enormous cleaning capacity eliminating the need for other cleaning agents and, very

possibly, further mechanical cleaning. Such high concentrations are extremely effective in killing a wide spectrum of bacteria such as oral microflora, including: Actinomyces viscosus, alpha Streptococcus, Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus epidermidis and Streptococcus mutants. Notwithstanding, if desired, the dental composition of the present invention may contain at least one antibacterial ingredient for exterminating bacteria that lead to the formation of plaque and tartar.

Once in a mouth, the dental composition of the present invention combines with saliva to form a solution and begins to remove dental biofilm from teeth, gums and gum lines, as well as the tongue and throat regions by both chemical and mechanical action. Similarly, liquid, gel, paste, spray and other forms of the dental composition are capable of removing dental biofilm from these various mouth and throat regions of the body. The amount of time that the dental composition must remain in the mouth to be effective will depend on the concentration of the composition and the form of the product which contains the composition. For example, many dental powder forms of the invention will usually begin to remove plaque and tartar in less than about 60 seconds; whereas a similar concentration of the composition in a toothpaste form can take slightly longer.

The dental composition of the present invention can also remove dental biofilm and calculus from between teeth, and in other small crevices in the mouth, depending on the size of the opening or crevice and the strength of the composition. The invention often eliminates the need for additional cleaning agents and the mechanical action of scrapers and other dental tools on exposed surfaces in the mouth and throat regions. However, if necessary or desired, dental tools can be used in combination with the claimed invention in order to remove calculus from areas in the mouth which are not readily exposed. Further, the amount and/or size of the ascorbic acid particles can be varied in order to comfortably achieve the desired taste and effectiveness. Moreover, the invention is highly efficient in preventing plaque accumulation and tartar formation if used consistently.

Individuals usually brush their teeth for less than 60 seconds during each brushing session thereby limiting the exposure time teeth have to the chemical and mechanical actions caused by toothpaste and a toothbrush. Most dentists and oral hygienists recommend longer treatments for efficient plaque removal. The dental composition of the present invention works quickly to remove dental biofilm, plaque and/or tartar, resulting in smooth teeth surfaces as well as clean gums, tongue and throat regions. Furthermore, ascorbic acid softens plaque formed between teeth and loose gums. Plaque accumulation is also inhibited in these areas resulting in

tighter gum lines and fresher breath. As a consequence, dental caries and periodontal diseases are effectively prevented.

By removing plaque and tartar from teeth in a mouth, the dental composition may eventually expose some enamel on the teeth. Because there is some evidence that long exposure of high concentrations of ascorbic acid may be harmful to tooth enamel, the dental composition of the present invention can also comprise an enamel-strengthening component to protect the enamel. The enamel-strengthening component can be any component known or yet to be discovered that protects tooth enamel. Preferably, the enamel-strengthening component is hydroxyapatite, a phosphate compound, or a fluoride compound. For example, the phosphate compound can be sodium monofluorophosphate and the fluoride compound can be ammonium fluoride, sodium fluoride or stannous fluoride. It is also preferred that the concentration of the enamel-strengthening component is less than about 1.0% by weight, most preferably, less than about 0.5% by weight. The enamel-strengthening component adheres to exposed surfaces in the mouth and promotes the recalcification and strengthening of teeth. The enamel-strengthening component is capable of being used effectively in dental filling methods for protecting, restoring and/or repairing pits, fissures and lesions in tooth enamel. Preferably, the enamel-strengthening components of the present invention also effectively absorb dental plaque.

As a result of containing an effective amount of an enamel-containing component, the composition of the present invention will not compromise, and instead will tend to repair, tooth enamel. Additionally, in one exemplary embodiment of the present invention, any mouth irritation, such as oral mucosa, that may be caused by the ascorbic acid can be easily treated by adding menthol to the dental composition.

In addition to containing an effective amount of ascorbic acid and an enamel-containing component, the dental composition of the present invention can, if desired, contain other ingredients including one or more of an abrasive agent, antibacterial agent, alcohol, bioactive material, carrier material, cellulose, coloring agent, filler material, fluoride, flavoring agent, glycerin, menthol, phosphate, silica, sodium benzoate, sodium carbonate peroxide, sodium saccharine, sweeteners, triclosan, thymol, water, whitening agent and zinc citrate.

For example, the dental composition can contain sodium bicarbonate and/or pumice where additional abrasiveness is desired. If desired, sweeteners, flavoring and coloring agents can also be added to achieve different tastes and flavors. Suitable sweeteners include, but are not limited to, sodium saccharine, aspartame, cyclamates, sucrose, sorbitol, mannitol, and maltitol. The preferred sweetener is sodium saccharine (0.01-0.02%). Also, suitable flavoring

agents include both natural and synthetic oils such as cinnamon oil, wintergreen oil, bay oil, citrus oil, lemon oil, lime oil and clove oil. Preferably, the dental composition is flavored with spearmint or peppermint in an amount of about 0.2%-0.4% by weight and, most preferably, spearmint and peppermint are combined in an amount of about 0.2%-0.4% by weight.

Bioactive ingredients or medications include, but are not limited to, antifungal, anti-inflammatory, antibiotic, anti-bacterial, analgesic and immunosuppressive agents. Also, ascorbic acid is a natural whitener, eliminating the need for additional whitening agents. However, if desired, the dental composition of the present invention can include such additional whitening ingredients as sodium carbonate peroxidase (about 3-5%) and hydrated silica (about 5-7%). Further, it is preferred that, when triclosan is added to the dental composition, its concentration be about 0.1% to about 0.5% by weight, most preferably 0.3% by weight.

The harmless nature of the present invention makes it even more suitable for use by children. Since many children do not regularly or efficiently brush their teeth, the present invention solves this problem by providing a safe, healthy and efficient dental composition and cleaning procedure eliminating the need for long and extensive brushing.

Since ascorbic acid is a preservative, the dental composition of the present invention need not be specially stored or packaged in sealed containers. Given the invention's preserving characteristics, its solutions can be made with tap water without compromising the solutions' cleaning properties; however, purified water is preferred. Also, the dental composition of the invention can contain additional preservatives such as sodium benzoate in an amount of about 0.2-0.4%.

In addition to dental compositions, the present invention is also directed to a dental method comprising the steps of taking into a mouth an effective amount of a dental composition comprising ascorbic acid; maintaining the dental composition in the mouth for a sufficient period of time; and expectorating the dental composition from the mouth. If desired, the dental method can further include rinsing the mouth with, for example, water or another form of mouth wash; and expectorating the rinse from the mouth. Additionally, various dental tools, including those previously described, can be employed with this dental method. These steps can also be repeated and, if performed on a consistent basis, will effectively remove and inhibit the formation of dental calculus in a mouth and throat region of a body. This same method can also be used effectively to treat gum disorders, prevent gum disorders, or both. Such gum disorders include, but are not necessarily limited to, caries, gingivitis and periodontitis.

EXAMPLES

The invention is now described in further detail with respect to the following examples. The examples are only illustrative examples, containing approximate percentages of various ingredients, and are not intended to be considered as limitations of the invention.

Example 1

A dental powder containing:

75%	ascorbic acid;
20%	tricalcium phosphate;
0.1-0.2%	menthol;
5%	zinc citrate.

Example 2

A medicated chewing gum containing:

69.0%	macticatory gum core;
20.0%	ascorbic acid;
0.1%	sodium saccharine;
0.5%	hydroxyapatite;
0.2%	spearmint/peppermint flavor;
0.24%	sodium fluoride;
0.001%	blue #1;
5.0%	zinc citrate trihydrate;
2.0%	sucralose;
1.0%	polymer coating for sugar-free chiclets;
0.1%	sodium benzoate;
1.0%	titanium dioxide;
0.85%	other ingredients.

Example 3

The tooth powder containing:

70.0%	ascorbic acid;
12.0%	tricalciumphosphate or dicalciumphosphate;
0.1%	menthol natural crystalline powder;
0.2%	spearmint/peppermint flavor;
0.24%	sodium fluoride;
3.0%	sodium carbonate peroxide;

5.0% hydrated silica;
5.0% zinc citrate trihydrate;
2.0% sucrose;
0.5% hydroxyapatite;
1.0% titanium dioxide;
0.96% other ingredients.

Example 4

An alcohol-free mouthwash containing:

25.0% ascorbic acid;
0.01% sodium saccharine;
0.2% spearmint/peppermint flavor;
0.001% blue #1;
5.0% zinc citrate;
0.7% cethylpyridium chloride;
10.0% glycerin;
0.1% polymer 407;
0.5% hydroxyapatite;
58.0% deionized water;
0.48% other ingredients.

Example 5

A mouthwash containing:

20.0% ascorbic acid;
10.0% sorbital solution;
0.01% sodium saccharine;
0.2% sodium benzoate;
0.2% spearmint/peppermint flavor;
0.0001% blue #1;
5.0% zinc citrate;
0.5% hydroxyapatite;
10.0% glycerin;
0.1% paloxamer 407;
0.24% sodium fluoride;
0.1% menthol in denatured alcohol;

0.1% thymol in denatured alcohol;
20.0% denatured alcohol with menthol and thymol;
33.0% deionized water;
0.55% other ingredients.

Example 6

A toothpaste containing:
34.0% ascorbic acid;
10.0% sorbital powder;
0.5% hydroxyapatite crystals;
0.01% sodium saccharine;
0.2% sodium benzoate;
0.2% spearmint/peppermint flavor;
5.0% zinc citrate trihydrate;
30.0% glycerin anhydrous;
0.24% sodium fluoride;
3.0% calcium orthophates;
5.0% hydrated silica;
10.0% tricalcium phosphate;
1.0% sodium lauryl sulfate;
0.85% other ingredients.

Example 7

An antiseptic gargle containing:
28.0% ascorbic acid;
0.2% sodium benzoate
0.6% menthol in denatured
0.05% methyl salicylate
0.1% thymol in denatured alcohol
20% denatured alcohol with menthol and thymol
0.2% sodium benzoate
1.0% hydroxyapatite
49.85% deionized water

Although the embodiments of the present disclosure have been described with specific examples, it is to be understood that the disclosure is not limited to those specific examples and that various other changes, combinations and modifications will be apparent to one of ordinary skill in the art without departing from the scope and spirit of the invention which is to be determined with reference to the following claims.

CLAIMS

We claim:

1. A dental composition comprising an effective amount of ascorbic acid.

2. The dental composition of claim 1, wherein the composition further comprises an enamel-strengthening component.

3. The dental composition of claim 1, wherein the concentration of the ascorbic acid is greater than about 50% by weight of the composition.

4. The dental composition of claim 1, wherein particles of the ascorbic acid are greater than about 5 microns in size.

5. The dental composition of claim 1, wherein the composition has a pH less than about 5.5.

6. The dental composition of claim 2, wherein the enamel-strengthening component is selected from the group consisting of at least one of hydroxyapatite, a phosphate compound, and a fluoride compound.

7. The dental composition of claim 6, wherein the fluoride compound is selected from the group consisting of ammonium fluoride, sodium fluoride and stannous fluoride.

8. The dental composition of claim 6, wherein the phosphate compound is sodium monofluorophosphate.

9. The dental composition of claim 2, wherein the enamel-strengthening component repairs damage to teeth.

10. The dental composition of claim 1, further comprising at least one of the ingredients selected from a group consisting of an abrasive agent, antibacterial agent, alcohol, bioactive material, carrier material, cellulose, coloring agent, filler material, fluoride, flavoring agent, glycerin, phosphate, silica, sodium benzoate, sodium carbonate peroxide, sodium saccharine, sweetener, triclosan, water, whitening agent and zinc citrate.

11. The dental composition of claim 10, wherein the concentration of triclosan is from about 0.1% to about 0.5% by weight of the composition.

12. The dental composition of claim 1, wherein the composition is a component of a dental product selected from the group consisting of breath spray, chewing gum, dental powder, gargle, lozenge, mouth spray, mouth wash, tooth gel, tooth liquid, and toothpaste.

13. The dental composition of claim 1, wherein the composition is impregnated in a dental tool.

14. The dental composition of claim 13, wherein the dental tool is selected from the group consisting of dental floss, a toothbrush, tooth strips and dental instruments.

15. The dental composition of claim 1, wherein the composition treats teeth and gums of a mouth.

16. The dental composition of claim 15, wherein the treatment is at least one of cleaning teeth, whitening teeth, improving gum disorders, removing dental biofilm from the mouth, and removing tartar from the mouth.

17. A dental composition for removing and inhibiting at least one of dental biofilm, plaque and tartar from a mouth, comprising an effective amount of ascorbic acid.

18. The dental composition of claim 17, wherein the composition further treats teeth and gum disorders, prevents teeth and gum disorders or both.

19. A dental method comprising the steps of:

(a) taking into a mouth an effective amount of a dental composition comprising ascorbic acid;

(b) maintaining the dental composition in the mouth for a sufficient period of time; and

(c) expectorating the dental composition from the mouth.

20. The dental method of claim 19, further comprising the steps of:

(a) rinsing the mouth with a rinse; and

(b) expectorating the rinse from the mouth.

21. The dental method of claim 19, further comprising repeating steps (a), (b) and (c) to inhibit the formation of dental biofilm and tartar in the mouth.

22. The dental method of claim 19, further comprising the step of using a dental tool to remove dental biofilm and tartar from the mouth.

23. The method as claimed in claim 22, wherein the dental tool is selected from the group consisting of a toothbrush, tooth strips, dental floss and dental instruments.

24. The method as claimed in claim 22, wherein the dental tool is impregnated with the composition.

25. A method of treating gum disorders, preventing gum disorders or both, comprising the steps of:

(a) taking into a mouth an effective amount of a dental composition comprising ascorbic acid;

(b) maintaining the dental composition in the mouth for a sufficient

period of time; and

(c) expectorating the dental composition from the mouth.

26. The method of claim 25, further comprising the step of using a dental tool to remove dental biofilm, plaque and tartar from the mouth.

5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/079992

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K8/67 A61Q11/00 A61K31/375 A61K33/42 A61P1/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K A61Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, MEDLINE, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/207092 A1 (RIINA JOSEPH [US] ET AL) 6 September 2007 (2007-09-06) [0009], [0011], [0017], [0021], [0025]	1-26
P,X	US 2008/057007 A1 (LEONHARDT CHARLES [US] ET AL) 6 March 2008 (2008-03-06) claims 1-26	1-26
X	US 2 470 906 A (RALPH TAYLOR) 24 May 1949 (1949-05-24)	1,2,4-6, 9,10,12, 15-18
Y	powder and paste formulation of column 3 column 1, line 37 - column 2, line 9; column 2, line 46-53	1-26
Y	WO 99/20237 A (ZAKRYTOE AKTSIONERNOE OBSCHEST [RU]; RUDIN VSEVOLOD NIKOLAEVICH [RU];) 29 April 1999 (1999-04-29) page 2, line 7-31	1-26

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 January 2009	26/01/2009

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US2008/079992

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